

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re INTUNIV ANTITRUST)
LITIGATION) Lead Case No. 1:16-cv-12396-ADB
This Document Relates to *Indirect*)
Purchaser Actions)

)

**DEFENDANTS' JOINT OPPOSITION TO THE INDIRECT PURCHASER
PLAINTIFFS' MOTION FOR CLASS CERTIFICATION**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
I. INTRODUCTION	1
II. FACTUAL BACKGROUND.....	7
III. IPPs UNDERSTATE AND FAIL TO MEET THEIR BURDEN OF PROOF.....	7
IV. IPPs HAVE NOT SHOWN THAT COMMON ISSUES PREDOMINATE OVER INDIVIDUAL ISSUES.....	9
A. The Proposed Classes Include a Meaningful Number of Uninjured Members and IPPs Provide No Plan for Identifying Them or Allowing Defendants to Challenge Any Class Member's Alleged Injury.....	12
1. There Are Thousands of Uninjured Class Members and IPPs Have Provided No Plan to Identify Them.	13
a. Many Intuniv coupon users are uninjured.	13
b. Many brand loyalists are uninjured.....	15
c. The proportion of uninjured class members is greater than in <i>Asacol</i>	16
2. Defendants Intend to Challenge at Trial Whether Class Members Are Injured, and IPPs Provide No Plan For Them To Do So.....	16
B. IPPs Do Not Provide a Method of Proving Class-Wide Antitrust Impact	18
C. IPPs' Impact Theory Is Complex and Requires a "Searching Inquiry" Into the Theory's Viability.....	20
V. IPPs' PROPOSED CLASSES ARE NOT ASCERTAINABLE.....	22
VI. IPPs CANNOT CERTIFY A NATIONAL CLASS OR AN <i>ILLINOIS BRICK REPEALER</i> CLASS.....	27
A. IPPs Cannot Establish a Nationwide Consumer Class Under Massachusetts Law	28

1.	Massachusetts law does not apply to the claims of nationwide consumer class members with no discernable connection to Massachusetts.....	28
a.	A conflict of laws exists.....	29
b.	Massachusetts law does not apply to the claims of the class as a whole.....	31
2.	Certification of IPPs' Nationwide Consumer Class under Massachusetts law would violate the Due Process and Commerce Clauses.....	36
3.	IPPs lack Article III standing to assert Massachusetts law claims on behalf of class members from non- <i>Illinois Brick</i> repealer states.....	38
B.	IPPs Have Not Met the Requirements for Certification of an <i>Illinois Brick</i> Repeater Class.....	39
VII.	EVEN IF CERTIFIED, IPPs' PROPOSED CLASS(ES) MUST BE NARROWED.....	41
A.	IPPs Present No Evidence Of Antitrust Harm or Damages Arising From The TWi/Anchen Settlement.....	41
B.	IPPs Present No Evidence or Analysis of Any Damages Beyond Those Based on Liability Under the Antitrust Laws	42
C.	IPPs Have No Evidence To Support The Time Period For Their Proposed Classes.....	43
VIII.	CONCLUSION.....	45
	APPENDIX A.....	1

TABLE OF AUTHORITIES

Cases

<i>All. of Auto. Mfrs. v. Gwadosky,</i> 430 F.3d 30 (1st Cir. 2005).....	38
<i>Allen v. Wright,</i> 468 U.S. 737 (1984).....	38
<i>Allstate Ins. Co. v. Hague,</i> 449 U.S. 302 (1981).....	35
<i>Amgen, Inc. v. Connecticut Ret. Plans & Tr. Funds,</i> 568 U.S. 455 (2013).....	9
<i>Aronstein v. Mass. Mut. Life Ins. Co.,</i> 2016 U.S. Dist. LEXIS 54190 (D. Mass. April 22, 2016).....	31
<i>AstraZeneca AB v. UFCW (In re Nexium Antitrust Litig.),</i> 777 F.3d 9 (D. Mass. 2015)	passim
<i>Blades v. Monsanto Co.,</i> 400 F.3d 562 (8th Cir. 2005)	9
<i>BMW of North America, Inc. v. Gore,</i> 517 U.S. 559 (1996).....	38
<i>Bristol-Myers Squibb Co. v. Superior Court of Cal.,</i> 137 S. Ct. 1773 (2017).....	35
<i>Burger King Corp. v. Rudzewicz,</i> 471 U.S. 462 (1985).....	35
<i>Carrera v. Bayer Corp.,</i> 727 F.3d 300 (3d Cir. 2013)	22
<i>Castano v. Am. Tobacco Co.,</i> 84 F.3d 734 (5th Cir. 1996)	40
<i>Cole v. Gen. Motors Corp.,</i> 484 F.3d 717 (5th Cir. 2007)	40
<i>College of Dental Surgs. of P.R. v. Conn. Gen. Life Ins. Co.,</i> 585 F.3d 33 (1st Cir. 2009).....	8
<i>Comcast Corp. v. Behrend,</i> 569 U.S. 27 (2013).....	8, 42

<i>Cornwell Entm't, Inc. v. Anchin, Block & Anchin LLP,</i> No. 09-11708, 2013 U.S. Dist. LEXIS 74653 (D. Mass. May 28, 2013).....	31
<i>DeRosa v. Mass. Bay Commuter Rail Co.,</i> 694 F. Supp. 2d 87 (D. Mass. 2010)	8
<i>Gaidon v Guardian Life Ins. Co. of Am.,</i> 750 N.E.2d 1078 (N.Y. 2001).....	31
<i>Gariety v. Grant Thornton, LLP,</i> 368 F.3d 356 (4th Cir. 2004)	40
<i>Gorsey v. I.M. Simon & Co.,</i> 121 F.R.D. 135 (D. Mass. 1988).....	28
<i>Illinois Brick Co. v. Illinois,</i> 431 U.S. 720 (1977).....	passim
<i>In re Actos End-Payor Antitrust Litig.,</i> 848 F.3d 89 (2d. Cir. 2017).....	11
<i>In re Asacol Antitrust Litigation,</i> 907 F.3d. 42 (2018).....	passim
<i>In re Bridgestone/Firestone, Inc.,</i> 288 F.3d 1012 (7th Cir. 2002)	30
<i>In re Cardizem Antitrust Litig.,</i> 105 F. Supp. 2d 618 (E.D. Mich. 2000).....	11
<i>In re Graphics Processing Units Antitrust Litig.,</i> 527 F. Supp. 2d 1011 (N.D. Cal. 2007)	30
<i>In re Hydrogen Peroxide Antitrust Litig.,</i> 240 F.R.D. 163 (E.D. Pa. 2007).....	45
<i>In re Kosmos Energy Ltd. Sec. Litig.,</i> 299 F.R.D. 133 (N.D. Tx. 2014).....	8
<i>In re New Motor Vehicles Canadian Exp. Antitrust Litig.,</i> 522 F.3d 6 (1st Cir. 2008).....	9, 12, 20
<i>In re Pharm. Indus. Average Wholesale Price Litig.,</i> 230 F.R.D. 61 (D. Mass. 2005).....	28, 32, 34, 40
<i>In re Relafen Antitrust Litig.,</i> 221 F.R.D. 260 (D. Mass. 2004).....	28, 32, 36

<i>In re Skelaxin (Metaxalone) Antitrust Litig.,</i> 299 F.R.D. 555 (E.D. Tenn. 2014).....	28
<i>In re Terazosin Hydrochloride,</i> 220 F.R.D. 672 (S.D. Fla. 2004).....	11
<i>In re TFT-LCD (Flat Panel) Antitrust Litig.,</i> No. 07-1827, 2013 WL 4175253 (N.D. Cal. July 11, 2013)	30, 45
<i>In re Thalomid and Revlimid Antitrust Litig.,</i> 2018 U.S. Dist. LEXIS 186457(D.N.J. Oct. 30, 2018).....	12, 22, 41
<i>In re Wellbutrin XL Antitrust Litigation,</i> 2015 U.S. Dist. LEXIS 84444 (E.D. Pa. Aug. 5, 2015).....	23, 25, 28
<i>Lujan v. Defenders of Wildlife,</i> 504 U.S. 555 (1992).....	38
<i>Marlborough Holdings Grp., Ltd. v. Azimut-Benetti, SpA,</i> 505 F. App'x 899 (11th Cir. 2013)	31
<i>Mear v. Sun Life Assurance Co. of Can. (U.S.),</i> No. 06-12143, 2008 U.S. Dist. LEXIS 9593 (D. Mass. Jan. 24, 2008).....	29
<i>Moore v. Metro Group Prop. & Cas. Ins. Co.,</i> 2010 U.S. Dist. LEXIS 129205 (D.R.I. 2010).....	37
<i>Or. Waste Sys., Inc. v. Dep't of Envtl. Quality,</i> 511 U.S. 93 (1994).....	37
<i>P.R. College of Dental Surgeons v. Triple S Mgmt.,</i> 290 F.R.D. 19 (D.P.R. 2013)	9
<i>Pa. Emp. Benefit Tr. Fund v. Zeneca, Inc.,</i> 710 F. Supp. 2d 458 (D. Del. 2010).....	32
<i>Phillips Petroleum Co. v. Shutts,</i> 472 U.S. 797 (1985).....	35, 36, 37
<i>Pilgrim v. Universal Health Card, LLC,</i> 660 F.3d 943 (6th Cir. 2011)	28
<i>Reed v. Advocate Health Care,</i> 268 F.R.D. 573 (N.D. Ill. Sept. 28, 2009).....	19, 20
<i>Reicher v. Berkshire Life Ins. Co. of Am.,</i> 360 F.3d 1 (1st Cir.2004).....	29

<i>S. State Police Benevolent Ass'n v First Choice Armor & Equip., Inc.</i> , 241 F.RD.85 (D. Mass. March 9, 2007)	40
<i>Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline</i> , No. 04-5898, 2010 U.S. Dist. LEXIS 105646 (E.D. Pa. Sept. 30, 2010)	19
<i>Spurlin v. Merchs. Ins. Co. of N.H.</i> , 57 F.3d 9 (1st Cir.1995).....	29
<i>St. Pierre v. CVS Pharm., Inc.</i> , C.A. No. 13-cv-13202, 2016 U.S. Dist. LEXIS 18492 (D. Mass. Feb. 16, 2016).....	9
<i>Steel Co. v. Citizens for a Better Environment</i> , 523 U.S. 83 (1998).....	38
<i>Travelers Supply, Inc. v. Hilton Head Labs., Inc.</i> , 2008 U.S. Dist. LEXIS 106698 (D. Mass. 2008)	35
<i>Tyson Foods, Inc. v. Bouaphakeo</i> , 136 S. Ct. 1036 (2016).....	36
<i>Vista Healthplan, Inc. v. Cephalon, Inc.</i> , 2015 U.S. Dist. LEXIS 74846 (E.D. Pa. June 10, 2015)	passim
<i>Wal-Mart Stores, Inc. v. Dukes</i> , 564 U.S. 338 (2011).....	7, 8, 9
<u>Statutes</u>	
Fla. Stat. § 501.201	1
Fla. Stat. § 501.2105	31
M.G.L. 260, §5A.....	31
M.G.L. Ch. 93A	1, 2
Mo. Rev. Stat. § 407.010	1
Mo. Rev. Stat. § 407.025	31
N.H. Rev. Stat. Ann. § 358-A:10	31
N.H. Rev. Stat. Ann. § 358-A:3	31
N.H. Rev. Stat. Ann. § 508:4	31
N.Y. Gen. Bus. Law § 340.....	1

N.Y. Gen. Bus. Law § 349.....	31
Wis. Stat. § 133.03.....	1, 31
Wis. Stat. § 133.18.....	31

Other Authorities

Rest. 2d Conflict of Laws, § 145	31
Rubenstein, Newberg on Class Actions § 1:1 (5th ed. 2012)	36

Rules

Fed. R. Civ. P. 23.....	passim
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Defendants Shire LLC, Shire US, Inc. (collectively “Shire”), Actavis Elizabeth LLC, and Actavis Holdco U.S., Inc. (collectively, “Defendants”) hereby oppose the Motion for Class Certification filed by Indirect Purchaser Plaintiffs Tina Picone, Carmen Richard, Shana Wright, and Sherry Cummisford (collectively, the “IPPs” or “Plaintiffs”).¹

I. INTRODUCTION

This case arises out of Shire’s settlement of patent litigation with Actavis² concerning Intuniv®, Shire’s medication for attention deficit hyperactivity disorder (“ADHD”).³ Under the Shire/Actavis settlement, Actavis launched its generic Intuniv product on December 1, 2014, nearly nine years before the last of Shire’s patents is due to expire.

IPPs are consumer purchasers (*i.e.*, “indirect-purchasers”) of Intuniv who claim that the Shire/Actavis settlement violated state antitrust and consumer protection laws because Shire agreed to “pay” Actavis to delay the launch of generic Intuniv by almost two years. IPPs have asserted 25 causes of action against Shire and 15 against Actavis under the laws of five different states: Massachusetts, Florida, Missouri, New York, and Wisconsin.⁴ They now seek the certification – based only upon alleged antitrust violations and ***not*** any other state law claims – of

¹ On February 4, 2019, the Court granted Defendants’ motion to seal and their motion for leave to file excess pages in connection with their oppositions to the Motions for Class Certification by the Direct Purchaser and Indirect Purchaser Plaintiffs. Dkt. Nos. 158 and 159 (16-cv-12396-ADB).

² The term “Actavis” collectively refers to Defendants Actavis Elizabeth LLC and Actavis Holdco U.S., Inc. Actavis was formerly known as Watson Pharmaceuticals, Inc. (“Watson”). It adopted the Actavis name after acquiring the assets of Actavis Inc. in October 2012. The term “Old Actavis” may be used to refer to the original company before Watson’s acquisition. Shire settled with Actavis on April 25, 2013, after the case went to trial in the District of Delaware, but before the court issued its ruling.

³ IPPs’ Consolidated Amended Class Action Complaint (“CAC”) also refers to a separate, earlier settlement that Shire had reached with non-parties, TWi Pharmaceuticals, Inc. (“TWi”) and Anchen Pharmaceuticals, Inc. (“Anchen”) (the “TWi/Anchen Settlement”), but the claims that are the basis of IPPs’ Motion to do not rely upon that settlement. TWi and Anchen had an agreement to collaborate to market and sell their generic Intuniv product, and are referred to collectively herein as “TWi/Anchen.”

⁴ IPPs’ claims under the following state laws survived Defendants’ Motion to Dismiss, which the Court granted in part: Mass. Gen. Laws c. 93A, *et seq.*; the Florida Deceptive and Unfair Trade Practices Act (“FDUTPA”); Fla. Stat. § 501.201, *et seq.*; the Missouri Merchandising Practices Act (“MMPA”), Mo. Rev. Stat. § 407.010, *et seq.*; N.Y. GEN. BUS. LAW § 340, *et seq.*; and the Wisconsin Antitrust Act, Wis. Stat. § 133.03, *et seq.*

two classes:

Nationwide Consumer Class: For the period beginning November 15, 2012, to the present: (A) All persons who purchased brand or generic Intuniv in the United States for personal or household use, and who paid the purchase price themselves; and (B) All persons covered by commercial health insurance who purchased brand Intuniv in the United States for personal or household use, and who paid some of the purchase price pursuant to a co-payment or co-insurance provision.

Illinois Brick Repealer Class: For the period beginning November 15, 2012, to the present, all persons in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, Wisconsin, and the District of Columbia (A) who purchased brand or generic Intuniv in the United States for personal or household use, and who paid the purchase price themselves; and (B) all persons covered by commercial health insurance who purchased brand Intuniv in the United States for personal or household use, and who paid some of the purchase price pursuant to a co-payment or co-insurance provision.

Excluded from the Classes are: (1) third-party payors; (2) persons and entities who purchased directly from Defendants; (3) persons and entities who purchased only for resale purposes; (4) “flat co-pay” or “Cadillac Plan” customers who made purchases only via fixed dollar co-payments that do not vary between a branded pharmaceutical and a generic equivalent; (5) governmental entities; (6) Defendants, as well as their officers, directors, affiliates, legal representatives; and (7) the judge, justices, magistrates, or judicial officers presiding over this matter.⁵

The first of these two classes purportedly includes purchasers nationwide, and yet the class’s claims are predicated only on Massachusetts General Laws, Chapter 93A (“c. 93A”). The other is an “*Illinois Brick Repealer Class*” of purchasers in the 26 jurisdictions with so-called “*Illinois Brick repealers*,” *i.e.*, state laws that allow indirect purchasers to bring antitrust damage claims.⁶ IPPs fail to meet many of Rule 23’s requirements, and their remarkable request to certify a nationwide class – which includes consumers in states where indirect purchaser damage suits

⁵ IPPs’ Motion for Class Certification (Dkt. No. 146), pp. 1-2.

⁶ See Plaintiffs’ Memorandum of Law in Support of their Motion (“IPP Mem.”), p. 10. Because Plaintiffs are “indirect purchasers,” they cannot bring a claim for damages for a violation of the federal antitrust laws. See *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) (indirect purchasers of goods cannot recover damages from antitrust violators under federal law). They can only bring such claims under state laws that permit them by judicial interpretation of state law or by the passage of statutes known as “*Illinois Brick repealers*.”

are **barred** – is fatally flawed. These failures are discussed in detail below. One especially glaring shortfall is IPPs’ failure to satisfy, or even meaningfully address, Rule 23(b)’s requirement that common questions of law or fact predominate over individualized inquiries. That shortfall is fatal to IPPs’ Motion in light of the First Circuit’s recent, landmark decision in *In re Asacol Antitrust Litigation* (“*Asacol*”), 907 F.3d. 42 (2018), which IPPs effectively ignore despite its remarkable similarity to this case.⁷

Asacol’s significance cannot be overstated: it harmonizes a series of class certification decisions from the Supreme Court and the First Circuit. It is particularly relevant here, because the decision details what class action plaintiffs must do to satisfy Rule 23(b)(3)’s predominance requirement in pharmaceutical antitrust cases, like this one, that involve claims of delayed generic entry across a proposed class that includes a meaningful number of uninjured class members.⁸ Because defendants are not liable to class members who suffered no injury from the defendants’ alleged conduct, those uninjured class members must be identified and eliminated when liability is adjudicated. For this reason, *Asacol* requires plaintiffs to offer a reasonable and workable plan to show that they can prove at the liability stage of the litigation, that each member of the class was, *in fact*, actually injured by the alleged antitrust violation.⁹ As the First Circuit has made clear, a plaintiff cannot satisfy Rule 23 if such a plan (i) requires highly individualized inquiries that would predominate over common issues, and/or (ii) compromises the defendants’ constitutional right to challenge each individual plaintiff’s ability to establish

⁷ The First Circuit issued the *Asacol* decision before IPPs filed their Motion, and IPPs cannot claim they did not know about it. In fact, IPPs cite *Asacol* in passing, but they then inexplicably fail to address its primary holding or its application to this case. IPP Mem., p. 10, n. 52.

⁸ An uninjured class member is a class member who falls within the class definition, but suffered no injury / antitrust impact as a result of the defendant’s alleged antitrust violation.

⁹ *Asacol*, 907 F.3d at 53-56, 58.

antitrust impact.¹⁰ ¹¹ Merely presenting evidence of class-wide injury based on averages or other aggregations that may mask variations among class members is insufficient.¹²

Asacol's application to this case is obvious. IPPs' expert, Dr. Meredith Rosenthal, [REDACTED]

[REDACTED] a meaningful portion of the proposed classes could not have been injured by Defendants' alleged conduct either because (i) their use of coupons for brand Intuniv purchases eliminated any price advantage for them by purchasing the generic product; or (ii) they were "brand loyalists" who would have continued to purchase brand Intuniv (and paid the exact same amount for it) even if generic Intuniv were available earlier to them. [REDACTED], Defendants' expert, Professor James Hughes, [REDACTED]

[REDACTED]¹³ That is higher than even the 10 percent of uninjured class members that resulted in a reversal of class certification in *Asacol*.¹⁴

Yet IPPs do not even address *Asacol*, and they plainly do not meet any of its requirements. They fail to present any evidence that can be used to show that individual class members were, in fact, injured, and they present no plan to identify uninjured class members. Instead, IPPs rely entirely on Dr. Rosenthal's [REDACTED]

[REDACTED]¹⁵ IPPs also do nothing to protect Defendants' rights to challenge individual claims of injury. For these reasons alone, the

¹⁰ Antitrust "impact" is another way of saying injury-in-fact caused by an antitrust violation.

¹¹ See *id.*

¹² See *id.*, 54-56.

¹³ Declaration of Joshua S. Barlow, Esq. submitted herewith ("Barlow Decl."), Ex. 1 (Report of Professor James Hughes, Ph. D) ("Hughes Report"), ¶ 14.

¹⁴ *Asacol*, 907 F.3d at 52.

¹⁵ *Id.*, 54-56.

Court should deny IPPs' Motion.

IPPs' failures do not end there. There are several additional reasons for the Court to deny IPPs' request to certify the proposed classes:

IPPs Understate And Fail To Meet Their Burden of Proof. To obtain class certification, IPPs must submit evidence sufficient to establish that all of the requirements of Rule 23 have been met; they cannot rest on their pleadings. But that is exactly what IPPs do, as they improperly ask the Court to rely on mere inferences and presumptions without supporting evidence. This mistaken approach permeates IPPs' Motion and supporting brief, but it is particularly prevalent in their cursory arguments regarding ascertainability, predominance, and the choice of law for their proposed Nationwide Consumer Class.

IPPs' Proposed Classes Are Not Ascertainable. Because IPPs' class definitions are ambiguous and confusing, a consumer's membership in a class cannot be readily ascertained. Moreover, verifying membership would require highly individualized, administratively difficult factual determinations. To identify class members would require, for example, an assessment of historical drug purchase information for a six-year period, including the type of product purchased, date of purchase, location of purchase, form of payment, and healthcare plan details. Such an assessment would make it exceptionally difficult for the Court to independently determine class membership, which precludes certification.

A Nationwide Consumer Class Under c. 93A Cannot Be Certified. IPPs defy precedent by attempting to certify a nationwide consumer class under the law of a single state. Courts in this District and elsewhere have repeatedly rejected such classes, and for good reason. There plainly is no basis to apply Massachusetts law to *all* consumer purchasers throughout the country. First and foremost, the vast majority of any injuries suffered by consumers occurred

outside Massachusetts. Indeed, even among the named IPPs, no plaintiff suffered any injury in Massachusetts during the broadest class period supported by the evidence. Further, Defendants have no contacts with Massachusetts that can support a nationwide class governed by Massachusetts law. Under governing choice-of-law principles, therefore, IPPs' request must fail. Indeed, certifying a nationwide class under c. 93A that includes tens of thousands of consumers with no connection to Massachusetts – and no right to bring an antitrust action under the laws of their own states¹⁶ – would be constitutionally impermissible. In particular, to use the laws of a single state to impose liability nationwide for conduct that occurred outside that state, and that is not actionable under the laws of many other states, would violate the Due Process and Commerce Clauses of the United States Constitution. In addition, IPPs are from *Illinois Brick* repealer states and do not have Article III standing to bring state law antitrust claims on behalf of potential class members from states that do not have *Illinois Brick* repealer laws.

An *Illinois Brick* Repeater Class Cannot Be Certified. With respect to IPPs' proposed *Illinois Brick* Repeater Class, IPPs have failed to provide the comparative analysis of the laws of the states comprising their proposed *Illinois Brick* Repeater Class, including their so-called "freestanding" claims under state antitrust and consumer protection laws that they claim sweep beyond the scope of the Sherman Act. Without that analysis, and because such laws may vary considerably, the Court cannot properly evaluate this alternative class's compliance with Rule 23, and IPPs' Motion should be denied for this reason as well.

Any Class That Is Certified Must Be Much Narrower Than IPPs Propose. Even if the Court were otherwise inclined to certify a class, IPPs' proposed classes and their purported class-wide claims are too broad. First, IPPs present no rationale to attribute alleged class-wide

¹⁶ Because their state is not an *Illinois Brick* repealer state.

injury to Shire's settlement with TWi/Anchen – relating to a separate ANDA litigation – or any alleged unfair or deceptive conduct separate and apart from the alleged antitrust violations. Second, IPPs' proposed class period – November 15, 2012, to the present – goes beyond any reasonable time period supported by the evidence. The broadest possible class period finding any support in the factual record begins no earlier than April 25, 2013, the date on which Defendants are alleged to have entered into an anticompetitive agreement, and ends no later than June 1, 2015, the day before several Intuniv generics entered the market.

For these reasons, and those set forth in greater detail below, this Court should deny IPPs' Motion for Class Certification.

II. FACTUAL BACKGROUND

Defendants refer to and incorporate by reference the factual summary contained in the Defendants' Opposition to Direct Purchaser Plaintiffs' Motion for Class Certification.

III. IPPs UNDERSTATE AND FAIL TO MEET THEIR BURDEN OF PROOF.

“The Supreme Court has been clear that the party seeking certification bears the burden of demonstrating that the requirements of Rule 23 are satisfied.”¹⁷ Under Rule 23(a), IPPs must establish that joinder is impracticable, that there are questions of law or fact common to the class, that inclusion in the class can be readily ascertained, and that the named representatives have claims that are typical of the proposed class and will adequately represent absent class members.¹⁸ Under Rule 23(b)(3), they must establish that “questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods” for resolving this dispute.¹⁹

¹⁷ *AstraZeneca AB v. UFCW (In re Nexium Antitrust Litig.)* (“Nexium”), 777 F.3d 9, 36 (D. Mass. 2015) (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011)).

¹⁸ See Fed. R. Civ. P. 23(a).

¹⁹ Fed. R. Civ. P. 23(b)(3).

Rule 23 does ***not*** “set forth a mere pleading standard,” as IPPs seem to presume.²⁰

Rather, a plaintiff “must affirmatively demonstrate his compliance with the Rule – that is, he must be prepared to prove that there are ***in fact*** sufficiently numerous parties, common questions of law or fact, etc.,”²¹ and “also satisfy through ***evidentiary proof***²² at least one of the provisions of Rule 23(b).”²³ Contrary to IPPs’ suggestion, there is no presumption of any kind in favor of certification.²⁴ Indeed, the Court must “probe behind the pleadings” to satisfy itself, “after a ***rigorous analysis***, that the prerequisites of Rule 23(a) have been satisfied,” as well as those of Rule 23(b), whose “predominance criterion” for damages actions under Rule 23(b)(3) “is even more demanding.”²⁵

IPPs present little more than a cursory outline of Rule 23’s requirements paired with unsupported assertions that these requirements have been satisfied.²⁶ In so doing, IPPs fall far short of the quantum or type(s) of evidence needed to certify a class of consumers harmed by alleged anticompetitive behavior. As addressed in more detail below, IPPs have failed to present ***any*** evidence in support of (i) several aspects of their purported theory of class-wide antitrust harm, and (ii) critical parameters of their proposed class definitions. Each failure is reason

²⁰ *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011).

²¹ *Id.*, 350-51 (emphasis supplied).

²² Such proof must be in the form of ***admissible*** evidence for a court to afford it any weight. *Asacol*, 907 F.3d at 53 (“The fact that plaintiffs seek class certification provides no occasion for jettisoning the rules of evidence and procedure”); *DeRosa v. Mass. Bay Commuter Rail Co.*, 694 F. Supp. 2d 87, 95 (D. Mass. 2010) (“The court considers only admissible evidence in determining whether Rule 23’s requirements are met.”).

²³ *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013) (emphasis supplied).

²⁴ Compare IPP Mem., p. 11 (“At the class certification stage, ‘[d]oubts should be resolved in favor of class certification.’”) (internal citation omitted), with, e.g., *In re Kosmos Energy Ltd. Sec. Litig.*, 299 F.R.D. 133, 150-51 (N.D. Tx. 2014) (“The Supreme Court has announced a clear directive to plaintiffs seeking class certification – in any type of case – that they will face a ‘rigorous analysis’ by the federal courts, will ***not be afforded*** favorable presumptions from the pleadings or otherwise”) (emphasis supplied).

²⁵ *Comcast*, 569 U.S. at 33-34 (internal quotations omitted) (emphasis supplied). The First Circuit has echoed this sentiment, holding that reviewing a complaint alone is normally not enough to determine class certification. See, e.g., *College of Dental Surgs. of P.R. v. Conn. Gen. Life Ins. Co.*, 585 F.3d 33, 41-42 (1st Cir. 2009).

²⁶ IPP Mem., pp. 10-18.

enough for the Court to deny IPPs' Motion. *See In re New Motor Vehicles Canadian Exp. Antitrust Litig.* ("New Motor Vehicles"), 522 F.3d 6, 30 (1st Cir. 2008) (vacating class certification where the record was incomplete and expert support was "conclusory").²⁷

IV. IPPs HAVE NOT SHOWN THAT COMMON ISSUES PREDOMINATE OVER INDIVIDUAL ISSUES.

IPPs have not satisfied the predominance requirement of Rule 23 (b)(3), which requires "that common issues must predominate over individual issues in order to certify a class" seeking damages.²⁸ This criterion is far more demanding than the need to show the existence of common questions under Rule 23(a).²⁹ The First Circuit has held that "[i]n antitrust class actions, common issues **do not** predominate if the fact of [an] antitrust violation and the fact of antitrust impact cannot be established through common proof."³⁰ Defendants have a constitutional right "to challenge [at trial] each class member's proof that the defendant[s] [are] liable to that class member."³¹ Where, as here, a proposed class includes a meaningful number of uninjured members – [REDACTED]

[REDACTED] – and those uninjured class members cannot be identified using common proof while still protecting the defendants' rights, then

²⁷ See also *St. Pierre v. CVS Pharm., Inc.*, C.A. No. 13-cv-13202, 2016 U.S. Dist. LEXIS 18492, *8-12 (D. Mass. Feb. 16, 2016) (denying class certification where plaintiffs "submitted nothing beyond conclusory allegations" to illustrate claims and injury common to the proposed class and, thus, failed to survive "[t]he well-established 'rigorous analysis' required"); *P.R. College of Dental Surgeons v. Triple S Mgmt.*, 290 F.R.D. 19, 26-32 (D.P.R. 2013) (denying class certification where plaintiffs demonstrated a "complete failure to provide any detailed factual argumentation" and rested instead on "conclusive assertion[s]" of their satisfaction of Rule 23's requirements).

²⁸ *Asacol*, 907 F.3d at 51 (citing *Amgen, Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 469 (2013)).

²⁹ *New Motor Vehicles*, 522 F.3d at 20.

³⁰ *Id.* (citing *Blades v. Monsanto Co.*, 400 F.3d 562, 566 (8th Cir. 2005)); accord *Nexium*, 777 F.3d at 18. In addition, the party seeking class certification of antitrust claims under Rule 23(b)(3) must show that any resulting damages can be established by common proof. *New Motor Vehicles*, 522 F.3d at 20.

³¹ *Asacol*, 907 F.3d at 55 (citing *Wal-Mart Stores Inc.*, 564 U.S. at 366-67).

³² Hughes Report, ¶ 14. Unless otherwise indicated, the figures appearing in this Section are based upon IPPs' But For Generic Entry Scenario 2 because IPPs cannot attribute a generic launch prior to April 25, 2013, to an agreement between Shire and Actavis that caused any injury. *See* § VII. C., *infra*. [REDACTED]

Hughes Report, ¶

13, n. 17.

individual issues will predominate over common ones, and the class cannot be certified.

In *Asacol*, the First Circuit restated and clarified the predominance requirements that an antitrust plaintiff class must meet for certification in cases such as this one. There, a proposed class of indirect purchasers claimed that a drug manufacturer's conduct injured the class by precluding generic competition, thus preventing class members from purchasing a less expensive generic version of a brand drug. The First Circuit accepted the district court's finding that about 10 percent of the proposed class members were not injured because they would not have purchased the generic product, even absent the defendant's alleged misconduct. It found that number to be a meaningful one, and determined that (i) the defendant intended to exercise its constitutional right to challenge at trial its alleged liability to uninjured class members, and (ii) the plaintiffs had not put forth a mechanism that would allow the defendant to do so without requiring thousands of mini-trials.³³ Given that "thousands" of uninjured plaintiffs had been included in the class, the court further held that the plaintiffs had an obligation to provide a "reasonable and workable plan" to prove the injury-in-fact of each class member at the liability phase of the trial, sufficient to protect the defendants' constitutional rights. The plaintiffs' failure to provide such a plan was "fatal to their motion to certify."³⁴

In so holding, the First Circuit expressly rejected the notion that identifying the uninjured class members was simply a matter of post-trial claims administration that could be accomplished merely by having class members sign affidavits attesting to their injuries. The plaintiffs argued that this affidavit-only methodology was supported by the First Circuit's earlier decision in *Nexium*. The *Asacol* Court held to the contrary, "reject[ing] any invitation to rewrite *Nexium* as sanctioning the use of inadmissible hearsay to prove injury to each class member at or

³³ *Asacol*, 907 F.3d at 51-53.

³⁴ *Id.*, 52.

after trial.”³⁵ The court explained that “[t]he fact that plaintiffs seek class certification provides no occasion for jettisoning the rules of evidence and procedure,” or otherwise limiting the defendants’ ability to challenge each plaintiff’s ability to satisfy the elements of its claim.³⁶ Ultimately, the court would not permit “a class action against a defendant who was precluded from raising genuine challenges at trial to the assertion of liability by individual members of a class that was known to have members who could not be presumed to be injured.”³⁷

Asacol is controlling here and compels denial of IPPs’ Motion. IPPs’ request for certification falls short for the very same reason that the *Asacol* plaintiffs’ request fell short. Just like the putative indirect-purchaser class in *Asacol*, IPPs do not account for and address the meaningful number of uninjured class members in this case [REDACTED] (discussed below). Nor do they propose a “reasonable and workable plan” (or any trial plan at all) that will provide Defendants with the opportunity to challenge each plaintiff’s alleged injury *without* “caus[ing] individual inquires to overwhelm common issues.”³⁹ Instead, IPPs propose to show class-wide injury in fact with a model that

[REDACTED]
[REDACTED].⁴⁰ [REDACTED] was advanced by the plaintiffs in *Asacol*, but the First Circuit rejected it as incapable of showing that each particular class member

³⁵ *Id.*, 53.

³⁶ *Id.*

³⁷ *Id.*, 57.

³⁸ Hughes Report, ¶ 14.

³⁹ *Asacol*, 907 F.3d at 58 (vacating a class where the uninjured class members accounted for 10 percent of the class).

⁴⁰ Report of Dr. Meredith Rosenthal (“Rosenthal Report”), ¶ 21-27, Att. C; IPP Mem., p. 18. IPPs also claim that they may rely on a presumption of antitrust impact, and cite *In re Cardizem Antitrust Litig.*, 105 F. Supp. 2d 618, 649 (E.D. Mich. 2000), *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89 (2d. Cir. 2017), and *In re Terazosin Hydrochloride*, 220 F.R.D. 672, 696 (S.D. Fla. 2004) on this point. IPP Mem., p. 18. These cases are distinguishable and do not support IPPs’ argument because they contradict the prevailing First Circuit standard. See *Asacol*, 907 F.3d at 57 (refusing to presume impact).

suffered an injury in fact. Finally, contrary to the First Circuit's decision in *New Motor Vehicles*, IPPs fail to address the complexities of their antitrust impact theory by providing a sufficient basis for the Court to perform the "searching inquiry into the viability of that theory" that *New Motor Vehicles* requires.⁴¹ For each of these reasons, IPPs have not satisfied Rule 23(b)(3)'s predominance requirement, and the Court should deny their Motion.

A. The Proposed Classes Include a Meaningful Number of Uninjured Members and IPPs Provide No Plan for Identifying Them or Allowing Defendants to Challenge Any Class Member's Alleged Injury.⁴²

Asacol held that a proposed class cannot be certified when (i) it contains a meaningful number of uninjured class members, (ii) the defendant intends to challenge at trial whether, in fact, individual class members were injured by the alleged antitrust violation, and (iii) plaintiffs have not proposed a "reasonable and workable plan" to identify uninjured class members that protects the defendants' constitutional rights but does not cause individual inquiries to overwhelm common issues.⁴³

IPPs fail to satisfy (or even address) any of these requirements even though *Asacol* is directly on point. First, their proposed classes include several categories of uninjured class members that [REDACTED]

[REDACTED]⁴⁴ a number that is not *de minimis*, but is quite meaningful.⁴⁵ These uninjured class

⁴¹ *New Motor Vehicles*, 522 F.3d at 26.

⁴² Hughes Report, ¶ 14.

⁴³ See *In re Thalomid*, 2018 U.S. Dist. LEXIS 186457 at *39 (denying class certification, citing *Asacol*, and stating "similarly here, plaintiff have not provided an appropriate common method of proving injury-in-fact given the presence of brand loyalists."); *Asacol*, 907 F.3d at 53.

⁴⁴ At the request of IPPs' counsel, Dr. Rosenthal [REDACTED]

[REDACTED]. Hughes Report, ¶ 14, n. 20.

⁴⁵ In *Asacol*, the court explained "this is not a case in which a very small absolute number of class members might be picked off in a manageable, individualized process at or before trial. Rather, this is a case in which any class member may be uninjured, and there are apparently thousands who in fact suffered no injury," and cited *Nexium*, for

members include those who benefited from Shire's coupon program and "brand loyalists."⁴⁶ Second, Defendants will challenge at trial whether particular class members have been injured by Defendants' alleged antitrust violation given the impossibility of otherwise knowing which consumers will fall into one of the uninjured groups.⁴⁷ Despite this, IPPs did not even propose a trial plan, let alone one that can identify uninjured class members and would allow Defendants to challenge (by means of common evidence) individual class members' claims that they were injured by an antitrust violation.⁴⁸

1. There Are Thousands of Uninjured Class Members and IPPs Have Provided No Plan to Identify Them.

a. Many Intuniv coupon users are uninjured.

During the class period, Shire had an extensive coupon program that reduced insured consumers' payments for a 30-day regimen of brand Intuniv to \$15. [REDACTED]

[REDACTED]

[REDACTED]).⁴⁹ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Rosenthal [REDACTED]

[REDACTED]

the point that "[w]e thus define 'de minimis' in functional terms." *Asacol*, 907 F.3d at 53-54 (finding that 10 percent was beyond *de minimis*) (citing *Nexium*, 777 F.3d at 30).

⁴⁶ Consumers who purchase a brand drug even when a generic version is available are commonly referred to as "brand loyalists."

⁴⁷ See *Asacol*, 907 F.3d at 52-53 ("Here . . . the record is clear that plaintiffs do not propose to rely on unrebutted testimony to eliminate the question of injury-in-fact before trial. And, unlike in *Nexium*, defendants have expressly stated their intention to challenge any affidavits that might be gathered. Nor do plaintiffs point to any basis in the record for deeming all such challenges to be so implausible as to warrant a finding that we can consider the issue to be uncontested.").

⁴⁸ See IPP Mem., p. 20.

⁴⁹ Barlow Decl., Ex. 2 (SHIREINT0274284 – "Program Summary" tab).

⁵⁰ Hughes Report, ¶ 44.

[REDACTED]⁵¹

The prevalence of coupon-assisted purchases is significant because [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Applying this reasoning to the data shows that:

- [REDACTED] [REDACTED]⁵⁴ [REDACTED]
- [REDACTED]⁵⁵ [REDACTED]
- [REDACTED]⁵⁶ [REDACTED]
- [REDACTED] [REDACTED]

[REDACTED]

⁵¹ *Id.*

⁵² Hughes Report, ¶ 45. Dr. Rosenthal [REDACTED]

⁵³ Rosenthal Report, Att. C.5 (column 13), Att. C.6 (column 12).

⁵⁴ Hughes Report, ¶ 45.

⁵⁵ Hughes Report, ¶ 47. While [REDACTED] s [REDACTED], Rosenthal Report, Att. C.6 (column 6), [REDACTED] . *Id.*

⁵⁶ Rosenthal Report., Att. C.7; Hughes Report, ¶ 48.

⁵⁷ Hughes Report, ¶ 49; Barlow Decl., Ex. 3 (SHIREINT0215119) [REDACTED]).

[REDACTED]

[REDACTED] .⁵⁹

b. Many brand loyalists are uninjured.

The class also includes members who purchased, or would have purchased, only brand Intuniv after generic Intuniv became available, *i.e.*, “brand loyalists.” The parties agree that

[REDACTED].⁶⁰ While

Dr. Rosenthal [REDACTED]

[REDACTED]. Professor Hughes, [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED].⁶¹ Professor Hughes [REDACTED]

[REDACTED] [REDACTED]

[REDACTED].⁶² Once again, IPPs have not even attempted to provide a plan, using class-wide evidence, to identify and exclude consumers who would have switched to a generic version of Intuniv from those who would have remained brand loyal. As a result, determining which class members would have continued to use Intuniv upon generic entry will necessarily require individualized inquiries. Under *Asacol*, IPPs’ Motion fails on this basis alone.⁶³

⁵⁸ [REDACTED]

⁵⁹ Hughes Report, ¶ 52.

⁶⁰ Rosenthal Report, Att. C.10.b, C.11.b, C.12.b, and C.13.b (showing [REDACTED]). And [REDACTED]. Hughes Report, ¶¶ 59-60.

⁶¹ Professor Hughes [REDACTED]. Hughes Report, ¶¶ 61-62.

⁶² *Id.*, ¶ 66. [REDACTED]

⁶³ See *Asacol*, 907 F.3d at 51 (finding a class of indirect purchasers where 10 percent of the class were brand loyalists was unacceptable given that “[p]roof of injury . . . is a required element of a plaintiff’s case in an action such as this one.”); Hughes Report, ¶¶ 50-63.

c. The proportion of uninjured class members is greater than in *Asacol*.

Combining both uninjured coupon users and brand loyalists, uninjured class members under IPPs' "But-For Scenario 2" ([REDACTED])

([REDACTED]) account for [REDACTED]

[REDACTED]⁶⁴ In fact, the percentage of uninjured class members in this case is even larger than the percentage of uninjured class members in *Asacol*.⁶⁵

Professor Hughes' ([REDACTED])

[REDACTED]⁶⁶ Nonetheless, IPPs offer no methodology or plan to identify and exclude these uninjured class members from the classes.⁶⁷ This is reason enough for the Court to deny their Motion.

2. Defendants Intend to Challenge at Trial Whether Class Members Are Injured, and IPPs Provide No Plan For Them To Do So.

Defendants intend to exercise their rights to challenge at trial whether class members are injured. The records of IPP Cummisford provide an apt example of why Defendants have reason to challenge whether individual IPPs suffered any injury-in-fact. IPPs claim that

Ms. Cummisford was injured because she [REDACTED]

⁶⁸

Her records show, [REDACTED]

⁶⁴ Hughes Report, ¶ 14.

⁶⁵ *Asacol*, 907 F.3d at 58 (uninjured class members accounted for 10 percent of the class).

⁶⁶ Hughes Report, ¶ 14 n.20.

⁶⁷ *Id.*, ¶ 54.

⁶⁸ Ms. Cummisford personally claims her injury was that [REDACTED]

Barlow Decl., Ex. 4 (relevant excerpts of the deposition of Sherry Cummisford), pp. 39:8-20, 93:17-24.

[REDACTED] [REDACTED]
[REDACTED] .
Defendants will argue to the jury that these records [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. But regardless of how this inquiry is addressed on the merits, it will be highly individualized, and require an assessment of Ms. Cummisford's purchase records and cross-examination of her injury claims.

Individual inquiries like this will need to be repeated many thousands of times because Defendants plan to challenge class members' injury claims whenever there is reason to question whether a particular class member would have purchased and paid less for generic Intuniv in the "but for" world.⁷¹ Professor Hughes's analysis confirms the presence of a significant number of uninjured class members, as detailed above. Because there is no way to know *in advance* which class members were not injured, Defendants would likely have to examine every potential class member to test their claims of injury. As Judge Barron explained in *Asacol*, "Class members do not come pre-identified . . . and one does not ordinarily set out to find a needle in a haystack by

⁶⁹ Barlow Decl., Ex. 5 (relevant excerpts of Sherry Cummisford's pharmacy records), pp. IPP_INTUNIV_187.
[REDACTED]

⁷⁰

Id., pp. IPP_INTUNIV_000141, 44

[REDACTED] and p.

IPP_INTUNIV_000145 (

⁷¹ See *Asacol*, 907 F. 3d at 51-52 ("Inefficiency can be pictured as a line of thousands of class members waiting their turn to offer testimony and evidence on individual issues. Unfairness is equally well pictured as an attempt to eliminate inefficiency by presuming to do away with the rights a party would customarily have to raise plausible individual challenges on those issues.").

examining only ten percent of the straw.”⁷²

In light of Defendants’ intention to challenge each class member’s injury-in-fact (an essential element of IPPs’ antitrust claims), IPPs’ proposed classes “cannot be certified based on an expectation that [Defendants] will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact.”⁷³ To overcome this problem, IPPs were required to provide the Court with the tools it needs to articulate “a reasonable and workable plan for how that opportunity will be provided in a manner that is protective of [Defendants’] constitutional rights and does not cause individual inquiries to overwhelm common issues.”⁷⁴ But IPPs have not even attempted to provide the Court with anything of the kind, and their Motion must be denied.

B. IPPs Do Not Provide a Method of Proving Class-Wide Antitrust Impact.

IPPs provide no method of proving class-wide antitrust impact. They devote just eleven lines of their brief to explaining their theory of antitrust impact, culminating with the bald assertion that “[p]roof of class-wide antitrust impact can be accomplished relatively easily through well-accepted methodologies and using actual historical data of how Intuniv market dynamics would have changed had generic entry come earlier.”⁷⁵ These purportedly “well-accepted methodologies” refer to Dr. Rosenthal’s report. [REDACTED]

[REDACTED]

[REDACTED].⁷⁶

In *Asacol*, the First Circuit expressly rejected the use of an aggregate damages model, that, [REDACTED], relies entirely on averages to purportedly establish class-wide

⁷² *Id.*, 61 (Barron, J., concurring).

⁷³ *Id.*, 58.

⁷⁴ *Id.*; see also *id.*, 53-54 (Without a way of identifying uninjured class members through common proof, the “need to identify those individuals will predominate and render an adjudication unmanageable.”).

⁷⁵ IPP Mem., p. 18.

⁷⁶ Hughes Report, ¶¶ 29-35.

impact.⁷⁷ The court explained that accepting this methodology for purposes of certification “would fly in the face of the core principle that class actions are the aggregation of individual claims, and do not create a class entity or re-apportion substantive claims.”⁷⁸ As the court noted, if merely calculating average damages could qualify as common proof despite the unquestioned presence of uninjured class members, “there would be no logical reason to prevent a named plaintiff from bringing suit on behalf of a large class of people, forty-nine percent or even ninety-nine percent of whom were not injured, so long as aggregate damages on behalf of the ‘class’ were reduced proportionately.”⁷⁹

Where, as here, divergent groups of purchasers vary by plan, place, time, treatment plan, and preference, the use of averages to show class-wide damages leaves the central predominance question unanswered, because it does not provide a basis to determine antitrust impact for individual consumers.⁸⁰ By [REDACTED]

Dr. Rosenthal [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁷⁷ *Asacol*, 907 F.3d at 56.

⁷⁸ *Id.*

⁷⁹ *Id.*; see also Hughes Report, ¶ 32 ([REDACTED]); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline*, No. 04-5898, 2010 U.S. Dist. LEXIS 105646, *56-101 (E.D. Pa. Sept. 30, 2010) (rejecting use of an aggregate damages model to establish injury to each class member).

⁸⁰ *Sheet Metal Workers*, 2010 U.S. Dist. LEXIS 105646 at *102 (“Neither am I persuaded by the plaintiffs’ insistence that the yardstick methodology Dr. Rosenthal proposes is commonly accepted in antitrust cases. The fundamental ‘issue is not whether [the] techniques are generally accepted; it is whether they are appropriate when applied to the facts and data *in this case.*’”) (quoting *Reed v. Advocate Health Care*, 268 F.R.D. 573, 594 (N.D. Ill. Sept. 28, 2009)) (emphasis in original); Hughes Report, ¶¶ 33-36.

[REDACTED] .⁸¹ In other words, [REDACTED]

[REDACTED]
In short, Dr. Rosenthal's [REDACTED],

Without that, IPPs cannot meet their burden of showing impact on every member of the class, and their Motion must be denied.

C. IPPs' Impact Theory Is Complex and Requires a "Searching Inquiry" Into the Theory's Viability.

Binding precedent dictates that IPPs' complex impact theory must be given heightened scrutiny. In *New Motor Vehicles*, the First Circuit made clear that when a plaintiff's theory of antitrust impact is complex, as it is here, courts should apply a "searching inquiry into whether plaintiffs will be able to prove the pivotal elements of their theory at trial."⁸² On its face, IPPs' impact theory is based primarily on the over-simplified notion that generic drugs are cheaper than branded drugs. IPPs simply assume that class members must have been impacted by the Defendants' alleged conduct due to the class members' inability to benefit from lower-priced generic Intuniv during the alleged period of delay. While this theory may be straightforward, "intuitive appeal is not enough."⁸³ In fact, IPPs' theory ignores the complexities inherent in determining if there is class-wide impact, and IPPs fail to provide this Court with the tools needed to perform the "searching inquiry" of those complexities that the First Circuit requires.⁸⁴

As Professor Hughes explains, [REDACTED]

⁸¹ Hughes Report, ¶ 32; see *Reed v. Advocate Health Care*, 268 F.R.D. 573, 590-591 (N.D. Ill. 2009).

⁸² *New Motor Vehicles*, 522 F.3d at 25-26.

⁸³ *Id.*, 29.

⁸⁴ *Id.*, 26.

- [REDACTED]
- [REDACTED] .⁸⁵ [REDACTED]
- [REDACTED]
- [REDACTED]⁸⁶
 - [REDACTED],⁸⁷
 - [REDACTED];⁸⁸ and
 - [REDACTED]⁸⁹

To meet their predominance burden, IPPs must have common proof that class members who purchased brand Intuniv before the generic version launched on December 1, 2014, would have switched to the generic and paid less for it. As discussed above, IPPs cannot do so using Dr. Rosenthal's [REDACTED]. IPPs offer no other means to do so.

Neither IPPs nor Dr. Rosenthal [REDACTED]

[REDACTED] and do not provide the Court with sufficient data to conduct a "searching inquiry" into the viability of their impact theory. Thus, this Court must deny IPPs' Motion.

⁸⁵ Hughes Report, ¶ 39.

⁸⁶ *Id.*, ¶ 40.

⁸⁷ *Id.*

⁸⁸ *Id.*, ¶ 41-42.

⁸⁹ *Id.*, ¶ 43; Rosenthal Report, Att. C.10.b, C.11.b, C.12.b and C.13.b.

V. IPPS' PROPOSED CLASSES ARE NOT ASCERTAINABLE.

IPPs have not demonstrated that the composition of the proposed classes is readily ascertainable. Rule 23 has an “implied” requirement that the proposed class definition must be “definite.” This means that inclusion in and exclusion from the class can be readily ascertained by applying objective criteria. *In re Nexium Antitrust Litig.*, 777 F.3d 9, 19 (1st Cir. 2015) (“As an essential prerequisite of a class action, plaintiffs must show, by a preponderance of the evidence, that the class is currently and readily ascertainable based on objective criteria.”) (quoting *Carrera v. Bayer Corp.*, 727 F.3d 300, 306 (3d Cir. 2013)) (quotation marks omitted).⁹⁰ Courts must be able to apply those objective criteria in an administratively feasible manner, so that determining class membership will not require highly individualized inquiries leading to thousands of mini-trials.⁹¹ As the Third Circuit explained in *Carrera* – which the First Circuit cited favorably in *Nexium* – the class proponent must provide “evidentiary support” that the proposed “method for ascertaining” class membership “will be successful.”⁹²

Applying these principles, courts have refused to certify indirect purchaser classes in antitrust cases, similar to this one, because the proposed class was not ascertainable. See, e.g., *In re Thalomid and Revlimid Antitrust Litig.*, 2018 U.S. Dist. LEXIS 186457, at *57 (D.N.J. Oct. 30, 2018) (declining to certify a consumer class because the plaintiffs had failed to put forward a viable “mechanism for determining whether putative class members fall within the class definition”) (internal quotation omitted); *In re Wellbutrin XL Antitrust Litigation*, 2015 U.S.

⁹⁰ While the First Circuit has recognized that ascertainability is a requirement under Rule 23, it has not ruled upon an ascertainability challenge to a class certification.

⁹¹ See *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 74846, *33-35, 43-44 (E.D. Pa. June 10, 2015) (rejecting plaintiffs’ “assurance[s] that readily available records could be used to ascertain the identities of class members” because “Plaintiffs have failed to present any evidence that they have developed a methodology for ascertaining the identities of class members, aside from simply assuring the court that records of Provigil prescriptions exist. Nor have Plaintiffs presented any evidence to demonstrate that it is possible to ascertain class members in an administratively feasible manner without high individualized inquiry.”)

⁹² *Carrera*, 727 F.3d at 306-307.

Dist. LEXIS 84444, at *39 (E.D. Pa. Aug. 5, 2015) (decertifying the consumer class because “the [Plaintiff had] not shown by a preponderance of the evidence that it can ascertain . . . which individual consumers of generic XL are members of the class.”).⁹³ Here, IPPs do not propose a viable mechanism to ascertain the bounds of their class definitions based on common evidence.⁹⁴ Consequently, their proposed classes cannot be certified.

For several reasons, determining which consumers purchased Intuniv over such a long time period (more than six years), and then applying the myriad exceptions for either of the proposed classes would place an untenable burden on the Court and the proposed class, requiring extensive individualized inquiry.

First, the enormous breadth of both proposed classes and their many exceptions will make it extremely difficult to determine which individual consumers meet the class definitions.⁹⁵ That determination will depend on whether a specific consumer purchased Intuniv within specific parameters and under specific circumstances that cannot easily be verified. For instance, only generic Intuniv purchasers “who paid the purchase price themselves” are included. Class membership will also depend on: the form of payment (cash, Medicaid fixed fee, co-pay, or co-insurance);⁹⁶ the amount of the payment;⁹⁷ the date of purchase; whether a purchase was for

⁹³ In particular, the plaintiffs in *Wellbutrin* did not show there was readily available data to determine whether purchases fell within the proposed class definition, which had included, *inter alia*, an exclusion for “flat co-pay” purchasers – *i.e.*, purchasers who paid the same fixed co-pay for either the brand or generic version of the drug. *Wellbutrin*, 2015 U.S. Dist. LEXIS 84444 at *39.

⁹⁴ Hughes Report, ¶ 37.

⁹⁵ See *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 74846, at *59 (E.D. Pa. June 10, 2015) (recognizing the ascertainability problems created by a proposed indirect purchaser class with “many exclusions”).

⁹⁶ IPPs’ class definitions differentiate which cash purchasers and which co-payment or co-insurance purchasers are in the classes, and though not excluded *per se* from the class definitions, [REDACTED]

[REDACTED]. See Rosenthal Report, Att. C.1, Columns 2, 7, 10.

⁹⁷ Whether an individual is excluded for having a flat co-payment requires knowledge of their insurance plan. Hughes Report, ¶ 37. [REDACTED] r [REDACTED]

[REDACTED]. Barlow Decl., Ex. 6 (relevant excerpts of the deposition of Tina Picone), pp. 27:2-8 ([REDACTED])

“personal or household use;”⁹⁸ and the states in which the purchase occurred and the purchaser resided at the time.⁹⁹ Few consumers, if any, will be able to answer the necessary questions accurately without professional/legal assistance, and even that will sometimes not be enough.¹⁰⁰

The experience of IPP Picone (who was prepared and assisted by counsel) shows that the ascertainability problems faced by the proposed class are real and substantial. [REDACTED]

These examples confirm that individualized inquiry is needed to ascertain whether the criteria for class membership have been met. That inquiry will also require manually searching for other key information that is not available through pharmacy records. This type of inquiry cannot be done in an administratively feasible manner and undermines the efficiency of class adjudication.

⁹⁸ IPPs do not explain which purchases made for others do and do not qualify for class membership.

⁹⁹ Both of IPPs' proposed classes suffer from different deficiencies, described in § VI., *infra*. If IPPs' Nationwide Consumer Class under c. 93A fails, potential class members would have to prove that they are from an *Illinois Brick* repealer state. If the Repeater class is limited to those states in which a named plaintiff allegedly suffered an injury, it would further limit – and require additional individualized inquiry to determine – the number of class members.

¹⁰⁰ A chart setting forth a lengthy progression of questions that will need to be answered may be found in Appendix A attached hereto.

¹⁰¹ Barlow Decl., Ex. 6 (relevant excerpts of the deposition of Tina Picone), pp. 68:5-19.

¹⁰² Ex. 7 (relevant excerpts of Tina Picone's pharmacy records), pp. IPP_INTUNIV_000001-02.

¹⁰³ Barlow Decl., Ex. 7 (relevant excerpts of Tina Picone's pharmacy records), pp. BERTRANDS_COSTELLO_000001-02.

¹⁰⁴ Barlow Decl., Ex. 6 (relevant excerpts of the deposition of Tina Picone), pp. 27:2-8.

The most glaring example of the need for individualized inquiry involves consumers with “flat co-pay” or “Cadillac Plan” provisions in their insurance plans. IPPs have excluded these consumers because they would not have saved any money if generic entry had occurred during the period of alleged delay because their co-pay for brand and generic Intuniv would have been the same. But as a result, these consumers must be identified and excluded from the classes per the class definitions. The failure of plaintiffs to provide a method of doing so using common evidence has led courts to find that similar consumer classes were not ascertainable.¹⁰⁵ IPPs’ proposed classes face the same problem. While Dr. Rosenthal [REDACTED]

[REDACTED]

[REDACTED],¹⁰⁶ she [REDACTED]

[REDACTED]

That step does nothing to ascertain which Intuniv purchasers should be excluded from the class due to their flat co-pay and Cadillac Plans. Nor do pharmaceutical records generally include detail sufficient to determine if the insured has an excluded plan.¹⁰⁷

In addition, ambiguity in both of the proposed class definitions is a problem, especially the language of part (A), which restricts the class to persons “who paid the purchase price themselves.” On its face, the definition includes consumers who are covered by Medicaid, because they, no less than insured consumers, will sometimes pay their own money at the point-of-purchase in the form of copayments. But [REDACTED]

¹⁰⁵ See, e.g., *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 74846 at *15, 43-44; *In re Wellbutrin XL Antitrust Litig.*, 2015 U.S. Dist. LEXIS 84444 at *47.

¹⁰⁶ Rosenthal Report, Att. C.10.b, C.11.b, C.12.b, C.13.b ([REDACTED])

¹⁰⁷ Hughes Report, ¶ 37.

[REDACTED] .¹⁰⁸ [REDACTED]
further illustrating the facial ambiguity of the class definition.

Finally, the *Illinois Brick* Repealer Class definition is not definite and does not provide objective criteria to feasibly define which consumers meet the class definition. For instance, it refers to “persons in” the 26 listed jurisdictions. It is unclear whether the definition refers only to persons **residing** in those jurisdictions. If it does, it is unclear whether the class includes individuals currently residing in those jurisdictions or only individuals who resided in the jurisdiction at the time of the relevant purchase(s). It is also unclear whether the definition applies to individuals who currently live in an *Illinois Brick* repealer jurisdiction, but did not suffer any injury in that same repealer jurisdiction. Lastly, it is not clear whether the definition applies to individuals who purchased Intuniv in a repealer jurisdiction, but did not reside in a repealer jurisdiction at the time; if it does, determining the state of purchase for each absent class member presents yet another significant administrative burden. Without addressing these questions, the *Illinois Brick* Repealer Class is not ascertainable.

Other than by advancing the class definitions themselves, IPPs provide no objective criteria and common evidence from which one can ascertain which consumer purchasers are in the classes. While IPPs state that Dr. Rosenthal “further explains that identification of class members . . . is possible using common, objective criteria,”¹⁰⁹ [REDACTED]

[REDACTED] ”¹¹⁰ She [REDACTED]

[REDACTED] ¹¹¹ Similarly, IPPs’ general reference to pharmacy

¹⁰⁸ See Rosenthal Report, Att. C.1, C.2, C.8 (Yardstick inputs in C.8 rely on column 9 from C.1 and C.2 (“[REDACTED]”)).

¹⁰⁹ IPP Mem., p. 2.

¹¹⁰ Rosenthal Report, ¶ 5.

¹¹¹ *Id.*, ¶ 10.

records does not address the significant limits to those records. Nor does it provide any basis to conclude that such records can be used in an administratively feasible manner that will not call for overly burdensome individualized inquiries.¹¹²

In short, IPPs have not provided a reasoned approach to ascertain the classes using a methodology that employs common, objective evidence, as opposed to highly individualized inquiry. They have therefore failed to show that the classes they propose meet the ascertainability requirement of Rule 23, and their Motion must be denied.

VI. IPPs CANNOT CERTIFY A NATIONAL CLASS OR AN *ILLINOIS BRICK REPEALER* CLASS.

IPPs propose a Nationwide Consumer Class under c. 93A and, in the alternative, an *Illinois Brick* Repealer Class. Neither can be certified.

IPPs' proposed Nationwide Consumer Class cannot be certified for three reasons. First, under applicable choice-of-law principles, Massachusetts law does not apply to the claims of consumers nationwide with no connection to the Commonwealth, which comprise the vast majority of any potential claims here. Second, basing a nationwide class on Massachusetts law is not only inconsistent with applicable choice-of-law rules, but it would violate both the Due Process and Commerce Clauses of the United States Constitution. Third, IPPs lack standing to assert claims under Massachusetts law on behalf of absent class members in states without *Illinois Brick* repealers.

IPPs' alternative *Illinois Brick* Repealer Class also cannot be certified because IPPs have not done the rigorous analysis of state law variation that the law requires. IPPs must perform this analysis and prove that the laws of the states that allow indirect purchaser damage claims do not

¹¹² IPP Mem., p. 15. IPPs' unsupported assertion that class membership can be verified through "class members' own pharmacy records" falls far short of meeting their burden, and does not address potential class members whose pharmacy may not have sufficient records, whose pharmacy closed, or who do not recall which pharmacies they used or what sort of prescription plan they had, among others.

have material differences that will predominate over common issues. IPPs have failed here as well.

A. IPPs Cannot Establish a Nationwide Consumer Class Under Massachusetts Law.

IPPs' request that the Court certify a *Nationwide* Consumer Class under the laws of a single state that has no discernable connection to any of their claims is extraordinary. Courts have routinely rejected such requests. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 83 (D. Mass. 2005) (collecting decisions); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 276 (D. Mass. 2004) (rejecting attempt to apply one state's consumer protection law to "wholly out-of-state transactions").¹¹³ Governing choice-of-law principles, as well as constitutional boundaries, guide the selection of what law will govern claims of both the named representatives and absent class members. These principles do not permit certification of a nationwide class because Massachusetts law cannot be applied to consumers and transactions with no meaningful connection to the Commonwealth.

1. Massachusetts law does not apply to the claims of nationwide consumer class members with no discernable connection to Massachusetts.

IPPs bear the burden of proving what law applies to the class they seek to certify.¹¹⁴ To meet this burden, IPPs must provide a detailed, fact-based analysis of well-established conflict of

¹¹³ *See also Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 947 (6th Cir. 2011) (rejecting a nationwide class, and holding that "the place of the injury controls in a consumer-protection lawsuit, requiring application of the home-state law of each potential class member."); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 586 (E.D. Tenn. 2014) (rejecting the plaintiffs' attempt to apply Tennessee antitrust law to a nationwide class, and explaining that "[a]ntitrust class actions, especially in the pharmaceutical industry, focus on the place the injury occurred, which is where the plaintiffs were overcharged"); *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 74846, *108 (E.D. Pa. June 10, 2015) (holding that the consumer-protection law of the state where the purchase was made should control); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 136 (E.D. Pa. 2011) (same); *In re Intel. Corp. Microprocessor Antitrust Litig.*, 2010 WL 8591815, at *56-57 (D. Del. July 28, 2010) (rejecting the plaintiffs' attempt to apply California law to the claims of nonresidents, and instead holding that the law of the state in which purchases were made should control).

¹¹⁴ *Gorsey v. I.M. Simon & Co.*, 121 F.R.D. 135, 140 (D. Mass. 1988) (finding a burden on plaintiff to perform choice of law analysis for class certification).

laws principles.¹¹⁵ They must prove that at least one of the named IPPs has a claim under Massachusetts law, **and** that Massachusetts law can be properly applied to the Nationwide Consumer Class. They have done neither. Instead, IPPs merely include a footnote with the conclusory assertion that “[o]ut of state plaintiffs...may sue under c. 93A,” which they pair with misplaced arguments about personal jurisdiction.¹¹⁶ IPPs present **no** choice-of-law analysis. Under governing choice-of-law principles, it is clear that Massachusetts law cannot apply on a class-wide basis.

a. A conflict of laws exists.

There is no dispute that Massachusetts choice-of-law principles apply to this case.¹¹⁷ Under those principles, the Court must first determine if a conflict actually exists between the alternative laws of one or more jurisdictions on a claim-specific basis.¹¹⁸ Here, the statutory standards/remedies of Massachusetts law conflict directly with the laws of the 25 states that do not allow a similar antitrust damage remedy for indirect purchasers. In addition, meaningful differences exist between statutory standards/remedies under Massachusetts law and those jurisdictions implicated by an appropriate choice-of-law analysis for the named representatives – *i.e.*, the laws of states where IPPs now reside or resided and made purchases during the class period (Missouri, New York, Florida, [REDACTED],¹¹⁹ and Wisconsin¹²⁰).

¹¹⁵ IPPs have conceded that, although “fact intensive,” now is the time for the Court to conduct a choice of law analysis. *See* IPPs’ Omnibus Opposition to Defendants’ Motions to Dismiss (Dkt. No. 59), p. 33 (arguing that a choice-of-law analysis was premature at the time of Defendants’ Motions to Dismiss, but that “district courts are required to conduct a rigorous choice-of-law analysis at the class certification stage”) (internal quotation omitted).

¹¹⁶ IPP Mem., p. 10, n. 52 (incorrectly equating considerations reserved for an evaluation of personal jurisdiction, such as “purposefully avails” by “doing business in the Commonwealth,” to choice-of-law factors).

¹¹⁷ A federal court in a diversity action applies the choice of law rules of the forum state. *See Spurlin v. Merchs. Ins. Co. of N.H.*, 57 F.3d 9, 10 (1st Cir.1995).

¹¹⁸ *See Mear v. Sun Life Assurance Co. of Can. (U.S.)*, No. 06-12143, 2008 U.S. Dist. LEXIS 9593, at *15-16 (D. Mass. Jan. 24, 2008) (citing *Reicher v. Berkshire Life Ins. Co. of Am.*, 360 F.3d 1, 4 (1st Cir.2004)).

¹¹⁹ [REDACTED]. Barlow Decl., Ex. 8 (relevant excerpts of the deposition of Carmen Richard), p. 8:8-12. [REDACTED]

C. 93A is obviously in direct conflict with the laws of the 25 states that have not authorized indirect purchasers to bring antitrust claims notwithstanding *Illinois Brick*. Some states, including Massachusetts, by judicial interpretation or statute, have decided not to apply *Illinois Brick*'s holding with respect to state antitrust law claims. Such states permit indirect purchasers to recover damages for antitrust violations. Other states have declined to do so, leaving in place *Illinois Brick*'s bar against indirect purchaser antitrust damage claims. The conflict between the laws of these two camps "looms large" given that "[e]ach state had the ability to repeal *Illinois Brick* as to its local law" – "[s]ome chose yes" and "[s]ome chose no."¹²¹ "[C]ourts must respect these differences rather than apply one state's law to sales in other states with different rules."¹²²

Conflicts also exist between c. 93A and the statutory schemes of the named IPPs' home states. For example, differences among applicable statutes of limitation and measures of

¹²¹ *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1027-28 (N.D. Cal. 2007) (finding a conflict of laws between repealer and non-repealer jurisdictions and dismissing claims on behalf of a nationwide class under California's *Illinois Brick* repealer because "allowing a nationwide class based on California antitrust law would allow residents of some states who abide by *Illinois Brick* to have claims where their respective state governments have declined to allow them"); *accord In re TFT-LCD (Flat Panel) Antitrust Litig.*, No. 07-1827, 2013 WL 4175253, at *1 (N.D. Cal. July 11, 2013) ("It is clear that Texas law differs from California in this matter as Texas law does not allow indirect purchaser lawsuits while California law does. There exists, therefore, a conflict of laws.").

¹²² *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1018 (7th Cir. 2002) ("State consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules.").

damages constitute a “conflict” for purposes of evaluating choice of law.¹²³ Each and every statute from IPPs’ resident states conflict with c. 93A (and each other) in some regard.¹²⁴

b. Massachusetts law does not apply to the claims of the class as a whole.

Where, as here, substantive conflicts of law exist, “Massachusetts courts apply a ‘functional approach that responds to the interests of the parties to determine which law applies.’”¹²⁵ The factors employed include “(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship,¹²⁶ if any, between the parties is centered.”¹²⁷ Here, those factors weigh heavily in favor of applying the laws of the state in which a class member resides. No single state law – not Massachusetts or any other – can apply to the claims of all purported class members.

The circumstances of the named Plaintiffs are illustrative. They were “at all relevant

¹²³ See, e.g., *Aronstein v. Mass. Mut. Life Ins. Co.*, 2016 U.S. Dist. LEXIS 54190, at *16-17 (D. Mass. April 22, 2016) (finding that material differences include “potential damages” under the Massachusetts and New York statutes).

¹²⁴ C. 93A, the Wisconsin Antitrust Act, and [REDACTED] provide for attorneys’ fees awards to prevailing plaintiffs; fee awards are discretionary under FDUTPA, N.Y. GEN. BUS. LAW § 349, and the Missouri Merchandising Practices Act (“MMPA”). C. 93A, § 9(4); Wis. STAT. § 133.18; [REDACTED] FLA. STAT. § 501.2105; N.Y. GEN. BUS. LAW § 349(h); MO Rev. Stat. § 407.025. The Wisconsin Antitrust Act allows for mandatory trebling of damages, while each of the other relevant statutes provide for discretionary multiple damages awards, or, in the case of the FDUTPA and MMPA, no multiple damages at all. See Wis. STAT. § 133.18; c. 93A, § 9(3) (double or treble damages for willful conduct); N.Y. GEN. BUS. LAW § 349(h) (discretionary trebling up to \$1,000); [REDACTED]

[REDACTED] FLA. STAT. § 501.2105; Mo. Rev. Stat. § 407.025. The statutes are also governed by different limitations periods, ranging from three to six years. M.G.L. 260, §5A; *Marlborough Holdings Grp., Ltd. v. Azimut-Benetti, SpA*, 505 F. App’x 899, 906 (11th Cir. 2013); Wis. STAT. § 133.18(2); *Gaidon v. Guardian Life Ins. Co. of Am.*, 750 N.E.2d 1078 (N.Y. 2001); N.H. Rev. Stat. Ann. §§ 508:4, 358-A:3; MO Rev. Stat. § 516.120.

¹²⁵ *Aronstein*, 2016 U.S. Dist. LEXIS 54190, at *17 (internal quotation and citation omitted).

¹²⁶ This last factor – focusing on the locus of an ongoing, or once ongoing, relationship between the parties – is inapplicable in this circumstance to the extent it intended to be examined separately from the locations of the parties’ residence or injury. See Rest. 2d Conflict of Laws, § 145, Comment (e).

¹²⁷ *Cornwell Entm’t, Inc. v. Anchin, Block & Anchin LLP*, No. 09-11708, 2013 U.S. Dist. LEXIS 74653, at *8 (D. Mass. May 28, 2013) (quoting Restatement (Second) of Conflict of Laws § 145 (1971)).

times” residents of New York, [REDACTED], Florida, Missouri, or Wisconsin.¹²⁸ Their alleged injury – the payment of “a higher co-pay for Intuniv than patients typically pay for drugs when a generic option is available” – also occurred [REDACTED]

[REDACTED]) in New York, [REDACTED], Missouri, or Wisconsin.¹²⁹ In addition, *none of IPPs* [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]¹³¹ Based on these considerations, Massachusetts law would not apply to any of their claims. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 83-84 (holding that, because “state consumer protection statutes are designed to protect consumers rather than to regulate corporate conduct,” the “laws of the home states of the consumers govern.”).

Plaintiffs’ flawed proposal to extend the class period of November 15, 2012, to the

¹²⁸ Courts applying the same traditional choice of law principles as those adopted by Massachusetts have placed particular emphasis on the first factor, concluding that the “home state of the plaintiff should apply to claims under state consumer protection statutes.” *Pa. Emp. Benefit Tr. Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458, 472 (D. Del. 2010) (granting motion to dismiss class claims asserted under Delaware law by non-resident plaintiff consumers); *accord In re Relafen Antitrust Litig.*, 221 F.R.D. at 277 (rejecting the uniform application of Pennsylvania law to a multi-state class because “the Court considers the more significant contact in this context to be the location of the injury – that is, the location of the sales to the end payor plaintiffs.”).

¹²⁹ See CAC, ¶¶ 117, 119, 121, 123, 125, 127, 129, 131; Barlow Decl., Ex. 7 (relevant excerpts of Tina Picone’s pharmacy records), pp. IPP_INTUNIV_00001-02; Ex. 5 (relevant excerpts of Sherri Cumminsford’s pharmacy records), IPP_INTUNIV_05-06; Ex. 9 (relevant excerpts of Carmen Richard’s pharmacy records), IPP_INTUNIV_38; Ex. 10 (relevant excerpts of Shana Wright’s pharmacy records), IPP_INTUNIV_44-45, 55-56, 64, 68-69, 74, 76, 80, 83, 85, 92, 99-100, 105, 108, 110, 112, 114, 117, 121. [REDACTED]. *Id.*, Ex. 7 (relevant excerpts of Tina Picone’s pharmacy records), p. BERTRANDS_COSTELLO_000001. [REDACTED]. *Id.*, Ex. 6 (relevant excerpts from the deposition of Tina Picone), pp. 68:20-70:6.

¹³⁰ [REDACTED]

. IPP_INTUNIV_00040. [REDACTED]

Id.

¹³¹ See § VII. C., *infra*.

present does not change this basic analysis.¹³² Under that proposal, [REDACTED]

[REDACTED].¹³³ That singular

occurrence cannot support the application of Massachusetts [REDACTED]

much less to the claims of the other IPPs **and** to the claims of a nationwide class. Doing so would entirely ignore the breadth of the functional choice-of-law determination Massachusetts employs, which in all other aspects favors application of the laws of other jurisdictions.

With respect to the second factor – the place where the conduct causing the injury occurred – IPPs articulate absolutely no connection to Massachusetts.¹³⁴ And there is none. All of the conduct allegedly giving rise to IPPs' claims occurred elsewhere. For Shire, [REDACTED]

[REDACTED].¹³⁵ At all relevant times, [REDACTED]

[REDACTED].¹³⁶ A [REDACTED]

[REDACTED].¹³⁷ [REDACTED]

[REDACTED].¹³⁸ [REDACTED]

¹³² See § VII. C., *infra* (discussing problems with IPPs' proposed class period).

¹³³ Barlow Decl., Ex. 9 (relevant excerpts of Carmen Richard's pharmacy records), p. IPP_INTUNIV_00040; Rosenthal Report, pp. 9-10.

¹³⁴ See IPP Mem., p. 10, n. 10.

¹³⁵ Barlow Decl., Ex. 11 (relevant excerpts of the deposition of T. May), pp. 13:7-14:10, 18:4-16, 114:22-115:20, 116:10-13; Ex. 12 (relevant excerpts of the deposition of D. Banchik), pp. 101:19-102:6, 102:22-103:23; Ex. 13 (Affidavit of Angus Russell) ("Russell Aff."), ¶¶ 5-6.

¹³⁶ Barlow Decl., Ex. 11 (relevant excerpts of the deposition of T. May), p. 12:19-23; Russell Aff., ¶¶ 5-6.

¹³⁷ See Barlow Decl., Ex. 14 (relevant excerpts of the deposition of D. Buchen), pp. 138:18-139:4; Ex. 15 (Actavis_Int_0080444).

¹³⁸ Russell Aff., ¶ 2; Barlow Decl., Ex. 16 (U.S. Securities and Exchange Commission Statement of Changes in Beneficial Ownership of Securities for Acatvis, Inc. Form 4, dated Mar. 8, 2013).

[REDACTED]¹³⁹ Th[REDACTED]

[REDACTED]¹⁴⁰ [REDACTED]

[REDACTED],¹⁴¹ [REDACTED]

[REDACTED].¹⁴²

Each of these facts weighs against the application of Massachusetts law to IPPs' claims or those of absent class members.

Indeed, the only conceivable link to Massachusetts that IPPs allege is by way of the third factor of the choice-of-law construct (*i.e.*, the domicile or place of incorporation / place of business of the parties). However, “[c]ourts have generally rejected application of the law of a defendant’s principal place of business to a nationwide class.”¹⁴³ And, regardless of whether this factor could **ever** sustain a nationwide class under the laws of a single state, IPPs fall far short of establishing the necessary nexus between their claims and the Commonwealth. Shire US, Inc. and Shire LLC are incorporated under the laws of the states of New Jersey and Kentucky, respectively.¹⁴⁴ While, as IPPs point out,¹⁴⁵ Shire **presently** has its headquarters in Massachusetts, that was **not** the case during the relevant 2012-2015 time period when Shire’s U.S. headquarters

¹³⁹ Barlow Decl., Ex. 11 (relevant excerpts of the deposition of T. May), p. 49:4-23; Ex. 14 (relevant excerpts of the deposition of D. Buchen), pp. 151:15-152:23; Russell Aff., ¶ 7.

¹⁴⁰ The License Agreement between Shire and Actavis attendant to the settlement agreement [REDACTED]

[REDACTED] Barlow Decl., Ex. 17 (Settlement and License Agreement between Shire and Actavis, dated April 25, 2013).

¹⁴¹ See Barlow Decl., Ex. 18 (relevant excerpts of the deposition of Alicia Badali), p. 35:5-16.

¹⁴² See Barlow Decl., Ex. 19 (relevant excerpts of the deposition of Jennifer Wu), pp. 107:15-108:17.

¹⁴³ See n 128, *supra*. As courts have recognized, the mere residence of a defendant is typically superseded by the relative interests of the state in which the consumer resides. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 84 (“[I]t is tempting to apply the consumer protection laws of the states where defendants have their principal places of business to promote uniform results and the ease of managing a class,” but “the laws of the home states of the consumers govern.”).

¹⁴⁴ CAC, ¶¶ 21-22; Barlow Decl., Ex. 20 (Penn. Dept. of State, Application for Cert. of Authority for Shire US, Inc., dated Mar. 29, 2004); Ex. 21 (Comm. Of Kentucky, Annual Report for Shire LLC, dated June 11, 2018).

¹⁴⁵ IPP Mem., p. 10, n 52.

principally remained in Pennsylvania and [REDACTED]

[REDACTED]

[REDACTED]

¹⁴⁶ Moreover, each of the Actavis entities is incorporated under the laws of the state of Delaware, and, at all relevant times, Actavis's principal place of business was located in New Jersey.¹⁴⁷ Defendants' domiciles and places of business thus offer no support to IPPs' argument that Massachusetts law applies.

IPPs barely argue otherwise. Rather, and in a transparent effort to secure a tether to Massachusetts, no matter how strained, much of IPPs' perfunctory analysis improperly relies on standards for establishing personal jurisdiction (*e.g.*, the more attenuated notion of "purposeful availment"), instead of applicable choice-of-law principles.¹⁴⁸ These concepts are distinct, however, both in substance and purpose. "[C]hoice-of-law analysis – which focuses on *all* elements of a transaction, and not simply on the defendant's conduct – is distinct from minimum-contacts jurisdictional analysis, which focuses at the threshold *solely on* the defendant's purposeful connection to the forum" as it relates to the plaintiff's cause of action.¹⁴⁹ IPPs cannot avoid a factual record that provides no basis for applying Massachusetts law by simply addressing a different and irrelevant question. When analyzed under the correct framework,

¹⁴⁶ Barlow Decl., Ex. 22 (excerpts of Shire PLC 10-K for the period ending Dec. 31, 2015), p. 66; Ex. 11 (relevant excerpts of the deposition of T. May), p. 12:19-23; Russell Aff., ¶¶ 5-6.

¹⁴⁷ CAC, ¶¶ 23-24.

¹⁴⁸ See IPP Mem., p. 10, n. 52 (relying on the presence of some Defendants' "facilities" in Massachusetts as well as Defendants' sales to state Medicaid programs as evidence that Defendants "purposefully avail[ed] [themselves] of doing business in the Commonwealth"). Although Defendants have not contested personal jurisdiction here, even on that issue, IPPs are wrong to suggest that purposeful availment of Massachusetts would establish specific jurisdiction for consumer claims on a nationwide basis. *See Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S. Ct. 1773, 1781-83 (2017).

¹⁴⁹ *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 481-82 (1985) (emphasis supplied); see also *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985) ("The issue of personal jurisdiction over plaintiffs in a class action is entirely distinct from the question of the constitutional limitations on choice of law"); *Travelers Supply, Inc. v. Hilton Head Labs., Inc.*, 2008 U.S. Dist. LEXIS 106698, *13-14 (D. Mass. 2008) (granting motion to dismiss on choice of law grounds, stating that "the questions surrounding statutes of limitations (and, here, the choice-of-law issue), on the one hand, and personal jurisdiction, on the other, are separate and distinct."); *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 320 n.3 (1981) (Stevens, J., concurring).

Massachusetts law cannot apply to the claims of the entire class. The Court should, accordingly, deny IPPs' request that the Court certify a Nationwide Consumer Class under Massachusetts law.

2. Certification of IPPs' Nationwide Consumer Class under Massachusetts law would violate the Due Process and Commerce Clauses.

Applying Massachusetts law to a Nationwide Consumer Class would not only be inconsistent with Massachusetts choice-of-law rules, but it would violate limits imposed by the U.S. Constitution. Rule 23 is "fundamentally a procedural device" that cannot be leveraged to "abridge, modify, or enlarge any substantive right."¹⁵⁰ Certifying IPPs' Nationwide Consumer Class under Massachusetts law would create new substantive rights for the benefit of absent class members who reside, or made purchases, in non-repealer states. That result would exceed the bounds of the Due Process and Commerce Clauses of the U.S. Constitution.

Beginning with the Due Process Clause, the Supreme Court has held that a court may not apply a single state's laws to every claim in a proposed nationwide class when doing so "would be 'arbitrary or unfair' and thus 'exceed constitutional limits.'"¹⁵¹ Echoing the choice-of-law analysis undertaken above and imposing a constitutional baseline for how that analysis must be applied, the Supreme Court in *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, (1985) held that to apply the forum state's law to a nationwide class, the state "must have a 'significant contact or significant aggregation of contacts' to the claims by each member of the plaintiff class, contacts 'creating state interests,' in order to ensure that the choice of [forum state] law is not arbitrary or unfair."¹⁵² 472 U.S. at 811; *accord In re Relafen Antitrust Litig.*, 221 F.R.D. at 276-77 (holding that application the law of Pennsylvania, where a defendant's facility was located, "would be at

¹⁵⁰ Rubenstein, Newberg on Class Actions § 1:1 (5th ed. 2012); *accord Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1048 (2016) (noting that a class action cannot enlarge class members' substantive rights).

¹⁵¹ *Shutts*, 472 U.S. at 811 (reversing judgment in Kansas state court to the extent it applied to a putative class of 28,000 members in eleven states under Kansas law although the majority of the class members had no apparent connection to Kansas).

best a ‘novelty,’ and at worst a violation of constitutional limitations” under *Shutts*).¹⁵² In “considering fairness in this context, an important element is the expectation of the parties.”¹⁵³

As discussed above, there is no “aggregation of contacts” with Massachusetts that can make IPPs’ attempted nationwide application of Massachusetts law anything other than arbitrary. Indeed, the factual record shows no significant “state interest” on the part of Massachusetts at all.¹⁵⁴ Defendants were not incorporated or based there at the relevant times. None of the alleged acts or omissions underlying IPPs’ claims occurred there, and there is no evidence of any Massachusetts connection to the alleged wrongdoing. Nor is there any discernable “aggregation” of contacts, by Defendants or putative class members. To the contrary, [REDACTED]

[REDACTED]

[REDACTED]¹⁵⁵ The Defendants, therefore, had no reason to anticipate that Massachusetts law would somehow govern product sales to consumers throughout the United States that have no connection to Massachusetts, including in the 25 jurisdictions that do not authorize antitrust suits by indirect purchasers. To arbitrarily apply Massachusetts law to a nationwide class in this case would violate the Due Process Clause.

The nationwide application of c. 93A would also violate the Commerce Clause¹⁵⁶ by, in

¹⁵² See also *Moore v. Metro Group Prop. & Cas. Ins. Co.*, 2010 U.S. Dist. LEXIS 129205, *19-21 (D.R.I. 2010) (dismissing class action claim purportedly asserted under Rhode Island law on grounds that, *inter alia*, the fact of defendants incorporation and headquarters in Rhode Island was “insufficient to convey to Rhode Island a prevailing state interest in the current litigation” in light of the constitutional boundaries set forth in *Shutts*).

¹⁵³ *Shutts*, 472 U.S. at 822.

¹⁵⁴ See § VI. A. 1. b., *supra*.

¹⁵⁵ Hughes Report, ¶ 9, n. 8. The *Shutts* Court found that a similarly small proportion of transactions (in that case, less than 1 percent of the at-issue gas leases) related to the proposed forum state and, thus, its laws could not apply. *Shutts*, 472 U.S. at 800.

¹⁵⁶ The Commerce Clause vests Congress with the authority to “regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. This grant of exclusive federal power carries an implicit consequence for states’ powers. When states regulate commerce within their own borders, they cannot enact laws that discriminate against out-of-state economic interests absent congressional authorization. *Or. Waste Sys., Inc. v. Dep’t of Envtl. Quality*, 511 U.S. 93, 98 (1994).

effect, applying c. 93A extraterritorially. To do so would create claims for the benefit of indirect purchasers in jurisdictions that have chosen *not* to create such a remedy (*i.e.*, non-*Illinois Brick* repealer states). Pursuant to the Commerce Clause, “no State can legislate except with reference to its own jurisdiction.”¹⁵⁷ “[O]ne State’s power to impose burdens on [interstate commerce] is not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interests of other States.”¹⁵⁸ It is beyond dispute that the Massachusetts legislature could not mandate that c. 93A be given extra-territorial effect without violating the Commerce Clause. There is no rational or legal basis to allow IPPs, through certification of a Nationwide Consumer Class under Massachusetts law, to achieve the same end.

3. IPPs lack Article III standing to assert Massachusetts law claims on behalf of class members from non-*Illinois Brick* repealer states.

IPPs bear the burden of proving that Article III’s standing requirements are satisfied.¹⁵⁹ While courts have cautioned that assessment of a named class representative’s standing may be “superfluous [to] the Rule 23 commonality and predominance requirements,” these concepts intersect where the claims of putative class representatives are fundamentally different from the claims of certain absent class members.¹⁶⁰ That is certainly the case here, where absent class members from 25 states that have not enacted an *Illinois Brick* repealer have no claim under the laws of their own states, yet seek to become members of a Nationwide Consumer Class under the laws of Massachusetts, where they also have no claim.

¹⁵⁷ *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 570-71 (1996).

¹⁵⁸ *Id.*; accord *All. of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir. 2005) (“A state statute that purports to regulate commerce occurring wholly beyond the boundaries of the enacting state outstrips the limits of the enacting state’s constitutional authority and, therefore, is *per se* invalid.”)

¹⁵⁹ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 104 (1998). Article III of the Constitution contains a requirement of justiciability which limits the jurisdiction of Article III courts to active “Cases” and “Controversies.” U.S. Const. art. III, § 2, cl. 1. The inquiry has three elements: a plaintiff must allege “[1] personal injury [2] fairly traceable to the defendant’s allegedly unlawful conduct and [3] likely to be redressed by the requested relief.” *Allen v. Wright*, 468 U.S. 737, 751 (1984).

¹⁶⁰ *Asacol*, 907 F.3d at 49.

The First Circuit’s recent analysis of these related concepts in *Asacol* illustrates the fundamental faults in IPPs’ Nationwide Consumer Class. There, the First Circuit held that the question for standing purposes is: “[a]re the differences [between the claims of class members and those of the class representative(s)] that do exist the type that leave the class representative with an insufficient personal stake in the adjudication of the class members’ claims” or are the claims sufficiently “parallel” such that “success on one claim under one state’s law will more or less dictate success under another state’s law.”¹⁶¹ Here, the “differences” are not a matter of degree, they are existential. IPPs seek to certify a nationwide class under Massachusetts law so they can litigate antitrust claims on behalf of putative class members from 25 states who have no such claim under the laws of their own states.¹⁶²

IPPs have no Article III standing to do so. Unlike the plaintiffs in *Asacol*, IPPs are not looking to simply assert claims on behalf of absent class members who may themselves have a claim under Massachusetts law (e.g., Massachusetts residents who made purchases of brand or generic Intuniv in Massachusetts during the relevant time period). IPPs are, instead, looking to assert claims under Massachusetts law on behalf of consumers across the nation, many of whom would otherwise have ***no such claim at all***. Not surprisingly, IPPs have not cited any authority that supports their position.

B. IPPs Have Not Met the Requirements for Certification of an *Illinois Brick* Repeater Class

IPPs also have not satisfied their burden to certify their back-up proposed class, limited to the 26 jurisdictions that have *Illinois Brick* repealers. In addition to all of the problems discussed above regarding ascertainability and uninjured class members, IPPs cannot satisfy Rule

¹⁶¹ *Id.*

¹⁶² IPPs have not put forth a class representative from even one of those 25 states.

23(b)(3)'s predominance and superiority requirements because they did not provide a comparative law analysis to support certification under the laws of multiple states.

As the proponents of certification, "the burden is on plaintiffs to demonstrate through extensive analysis" of the relevant state laws so that the Court can determine whether material differences in relevant states' laws will predominate over common issues.¹⁶³ *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 84. IPPs have undertaken no such analysis, and instead rest on nothing more than conclusory statements that there are "substantial similarities" between the federal and state causes of action and that their relative elements "dovetail."¹⁶⁴ That is plainly inadequate to establish the predominance of common issues across the laws of the 26 jurisdictions that comprise IPPs' proposed *Illinois Brick Repeater Class*.¹⁶⁵

At a minimum, IPPs have not established that a class, including their proposed standalone state law claims that are not premised on underlying Sherman Act violations, can be certified. In its decision on Defendants' Motion to Dismiss, this Court noted that IPPs would need to "clarify the scope of the state law" for these claims.¹⁶⁶ But IPPs have not done so, and thus fundamentally fail to grapple with "significant differences between the states' consumer

¹⁶³ *Accord Cole v. Gen. Motors Corp.*, 484 F.3d 717, 726 (5th Cir. 2007) ("The party seeking [class] certification . . . must . . . provide 'an extensive analysis' of state law variations to reveal whether these pose 'insuperable obstacles.'") (internal quotation marks and citations omitted); *Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 370 (4th Cir. 2004) ("The plaintiffs have the burden of showing that common questions of law predominate, and they cannot meet this burden when the various laws have not been identified and compared"); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 742-43 n.15 (5th Cir. 1996) ("We find it difficult to fathom how common issues could predominate in this case when variations in state law are thoroughly considered."); *see also S. State Police Benevolent Ass'n v First Choice Armor & Equip., Inc.*, 241 F.R.D.85, 90 (D. Mass. March 9, 2007) (noting division of authority on the question of burden in this context, but concluding the better view allocates the burden to plaintiffs as the proponents of class certification).

¹⁶⁴ IPP Mem., pp. 16-17.

¹⁶⁵ *See Castano v. American Tobacco Co.*, 84 F.3d 734, 741 (5th Cir. 1996) ("In a multi-state class action, variations in state law may swamp any common issues and defeat predominance.").

¹⁶⁶ Memorandum and Order on Motions to Dismiss (Dkt. No. 92), p. 33 & n. 14.

protection statutes”¹⁶⁷ that arise if IPPs’ causes of action are not restricted to the scope of the Sherman Act and *FTC v. Actavis*, the seminal case applying the Act to antitrust claims about alleged delayed generic entry.

VII. EVEN IF CERTIFIED, IPPS’ PROPOSED CLASS(ES) MUST BE NARROWED.

IPPs have failed to offer any support for important aspects of their theories of antitrust harm and alleged class damages. Each failure warrants, at the very least, the Court’s narrowing of IPPs’ proposed classes and the issues and claims, if any, to be decided on a class-wide basis.

A. IPPs Present No Evidence Of Antitrust Harm or Damages Arising From The TWi/Anchen Settlement.

IPPs fail to present any evidence that Shire’s settlement with TWi/Anchen¹⁶⁸ independently constituted an unlawful agreement or that it caused class-wide antitrust harm and damages. IPPs state, and Defendants agree, that the existence of an anticompetitive “contract, combination, or conspiracy” is an essential element of IPPs’ claims.¹⁶⁹ IPPs allege the existence of only one agreement causally related to class-wide harm – a “no AG” agreement implicitly incorporated into the Shire/Actavis agreement.¹⁷⁰ While IPPs reference Shire’s agreement with TWi/Anchen in their “factual” summary, their only “evidence” that this agreement was part of a

¹⁶⁷ *In re Thalomid*, 2018 U.S. Dist. LEXIS 186457, at *53-56 (declining to certify an indirect purchaser class because, among other problems, the plaintiffs did not account for state-law variations in consumer protection laws); *see also Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 74846, *101-107 (E.D. Pa. June 10, 2015) (similar).

¹⁶⁸ Shire’s litigation settlement agreement with TWi/Anchen predated its settlement agreement with Actavis by roughly seven months and settled a different litigation. *See* Defendants’ Opposition to DPPs’ Motion to Certify Class, pp. 4-6 (setting forth more detail regarding Shire’s settlement with TWi/Anchen).

¹⁶⁹ IPP Mem., p. 17.

¹⁷⁰ Specifically, IPPs allege that Actavis agreed to delay its launch of generic Intuniv until December 1, 2014, in exchange for Shire agreeing to not launch an Intuniv authorized generic (“AG”) during Actavis’s 180 days of generic exclusivity (a “no AG” agreement). An AG is a generic, unbranded version of the brand manufacturer’s product that the brand manufacturer makes and sells to others for resale. A “no-AG agreement” is an agreement by the brand company not to market or sell an AG.

larger scheme is the inadmissible hearsay opinion of a financial analyst.¹⁷¹ IPPs fail to explain how the TWi/Anchen Settlement by itself led to class-wide antitrust harm by any measure.

IPPs' expert, Dr. Rosenthal, [REDACTED]

[REDACTED]⁷² [REDACTED]

[REDACTED]¹⁷³

IPPs thus present no evidence of antitrust injury independently flowing from the TWi/Anchen Settlement. And the basis for any such harm is not explained by IPPs or their expert. IPPs have therefore failed to carry their burden to establish a theory of class-wide harm attributable to the TWi/Anchen Settlement, and the Court should deny any request to certify a class based, in whole or in part, on that theory of liability.

B. IPPs Present No Evidence or Analysis of Any Damages Beyond Those Based on Liability Under the Antitrust Laws

IPPs have previously alleged that their claims under state law go beyond violations of the antitrust laws, reaching, for example, deceptive conduct not otherwise prohibited by the Sherman Act, but perhaps covered by state laws. They have provided no analysis or evidence to support those allegations, and their Motion speaks only to antitrust claims.¹⁷⁴ IPPs provided only an analysis of damages allegedly caused by violations of the antitrust laws that they are pursuing

¹⁷¹ IPP Mem., p. 5, n 27.

¹⁷² Rosenthal Report, p. 9 (emphasis added); *accord* IPP Mem., p. 9 (“common proof, will conclusively demonstrate that *Shire* and *Actavis* conspired to unfairly delay generic competition”) (emphasis supplied).

¹⁷³ See *Comcast*, 569 U.S. at 36 (reversing certification where “[t]here is no question that the model failed to measure damages resulting from the particular antitrust injury on which petitioners’ liability in this action is premised.”); *see also id.*, 38 (“The first step in a damages study is the translation of the legal theory of the harmful event into an analysis of the economic impact of that event”) (quoting Federal Judicial Center, Reference Manual on Scientific Evidence 432 (3d ed. 2011)).

¹⁷⁴ IPP Mem., pp. 13 (“Plaintiffs and class members all have claims based on a common antitrust legal theory”) and 18-19.

through laws of states that have an *Illinois Brick* repealer. Without an economic, damages, or other analysis tying other liability theories to specific damages linked to those theories, IPPs cannot certify class claims that encompass those theories of liability.¹⁷⁵ Moreover, as explained above, IPPs have made no effort to address the variations in state consumer protection claims to the extent those claims may redress conduct beyond the scope of the Sherman Act.¹⁷⁶ Thus, to the extent IPPs can otherwise satisfy the requirements for class certification, any class that is certified must be limited to members harmed by the Defendants' alleged antitrust violations, and the damages that those alleged violations caused to those class members.

C. IPPs Have No Evidence To Support The Time Period For Their Proposed Classes.

IPPs have provided no evidence to support the expansive time period – “November 15, 2012, to the present” – during which they allege class-wide damages have accrued. As for the beginning boundary of November 15, 2012, IPPs offer no factual basis at all to justify a class damages period that begins *before* Actavis and Shire entered into the Shire/Actavis settlement (April 25, 2013). To the extent IPPs’ use of November 15, 2012, is based on presumptions about Actavis’s ability to launch “at-risk” and Shire’s readiness to supply AG Intuniv in the event an “at risk” launch by Actavis¹⁷⁷ those presumptions are left unexplained and unsubstantiated. An essential element of IPPs’ claims is the existence of an allegedly anticompetitive agreement, which undisputedly could not have existed prior to April 25, 2013, when Defendants entered into the Shire/Actavis agreement.¹⁷⁸ Therefore, the proposed class could not have suffered antitrust

¹⁷⁵ *Id.*

¹⁷⁶ See § VI. B., *supra*.

¹⁷⁷ See, e.g., Barlow Decl., Ex. 23 (relevant excerpts of the deposition of Leonard Fasullo), p. 191; Ex. 24 (Fasullo Dep. Ex. 11); Ex. 25 (Shire’s Responses and Objections to DPP’s Interrogatories, dated September 25, 2018), at No. 9.

¹⁷⁸ See IPP Mem., pp. 5-6, 17 (stating that the existence of an anticompetitive “contract, combination, or conspiracy” is an essential element of IPPs’ federal and state law claims).

injury pre-dating that agreement.¹⁷⁹

As for the end point for class damages, IPPs do not offer one, arguing instead that the class period extends “to the present.” IPPs’ position directly conflicts with the class period proposed by DPPs – a period ending on June 1, 2015, based on the actual entry of four additional generics around that date.¹⁸⁰ DPPs base that end point on [REDACTED]

[REDACTED]
[REDACTED].¹⁸¹ As IPPs have readily acknowledged, [REDACTED]

[REDACTED]
([REDACTED]).¹⁸² [REDACTED], any anticompetitive injury borne by IPPs necessarily requires anticompetitive effects occurring upstream, and allegedly affecting DPPs, that were passed through to IPPs.¹⁸³ The beginning and end of those alleged anticompetitive effects cannot logically be inconsistent with one another. Accordingly, IPPs have failed to establish that the class period extends through the present.

Absent any explanation or evidentiary support, the parameters of IPPs’ proposed class period(s) should not be accepted by the Court. The Court should at least modify the relevant

¹⁷⁹ It is also uncontested that any decisions by Shire or Actavis not to launch AG or generic Intuniv [REDACTED]

[REDACTED] . IPP Mem., p. 6 (

¹⁸⁰ See Report of DPPs’ Expert, Dr. Jeffrey J. Leitzinger (Dkt. No. 199-1, Case No. 16-12653) (“Leitzinger Report”), ¶¶ 21, 33, 43.

¹⁸¹ See *id.*

¹⁸² Rosenthal Report, ¶ 31 [REDACTED]

¹⁸³ *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 736 (1977).

class period to reflect start and end dates rooted in fact.¹⁸⁴ The only remotely defensible class period is one that begins sometime after April 25, 2013, the date when Shire and Actavis allegedly entered into an anticompetitive agreement, and ends before June 2, 2015, the date on which a fourth generic entered the market and, as DPPs conclude, the price of generic Intuniv had dropped enough to end any discernible overcharge.

VIII. CONCLUSION

For each of the foregoing reasons, this Court should deny IPPs' Motion for Class Certification.

¹⁸⁴ “The power of a district court to alter the definition or scope of a plaintiff’s proposed class is also well established among the lower federal courts.” Wolff, *Discretion in Class Certification*, 162 U. PENN. L. REV. 1897, 1918 (2014); *accord In re TFT-LCD Antitrust Litig.*, 267 F.R.D. 291, 302-3 (N.D. Cal. 2010) (shortening antitrust class period from 11 to 7 years); *In re Hydrogen Peroxide Antitrust Litig.*, 240 F.R.D. 163, 177 (E.D. Pa. 2007) (shortening proposed antitrust class period in light of plaintiffs’ “unsupported allegation[s]”).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Joshua S. Barlow, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on February 27, 2019.

/s/ Joshua S. Barlow
Joshua S. Barlow

APPENDIX A

THRESHOLD QUESTIONS/ EXCLUSIONS			
<p>Did you purchase brand and/or generic Intuniv?</p> <p>At what pharmacies did you purchase brand or generic Intuniv?</p> <p>Are you a third party payor or a government entity?</p> <p>Did you purchase Intuniv or generic Intuniv directly from Shire or Actavis?</p> <p>Did you purchase Intuniv or generic Intuniv only for resale purposes?</p> <p>Are you an officer, director, affiliate or legal representative of Shire or Actavis?</p> <p>Are you a judge, justice, magistrate, or judicial officer presiding over this matter?</p>			
QUESTIONS TO DETERMINE MEMBERSHIP IN ONE OR BOTH SUBCLASSES			
For each purchase of generic Intuniv:	Necessary to confirm class status?	Readily known by consumers?	Available from Rx Records?
When did you purchase generic Intuniv?	Yes	Sometimes	If provided
Did you pay the purchase price yourself?	Yes	Ambiguous	If provided
In what state did you purchase brand/generic Intuniv?	Possibly	Sometimes	If provided
In what state did you live at the time of purchase?	Yes	Sometimes	Sometimes, if provided
Was this purchase Intuniv for personal or household use?	Yes	Ambiguous	No
For each purchase of brand Intuniv:	Necessary to confirm class status?	Readily known by consumers?	Available from Rx Records?
When did you purchase Intuniv?	Yes	Sometimes	If provided
Did you pay the purchase price yourself?	Possibly	Ambiguous	If provided
Did you pay a co-pay or co-insurance?	Possibly	Sometimes	If provided
Did you have a flat co-pay or “Cadillac Plan”?	Yes	Sometimes	No
Did Medicaid cover the cost of your Intuniv purchase?	Yes	Sometimes	If provided
In what state did you purchase Intuniv?	Possibly	Sometimes	If provided
In what state did you live at the time of purchase?	Yes	Sometimes	Sometimes, if provided
Was this purchase Intuniv for personal or household use?	Yes	Ambiguous	No